THE SCANPOINT® UROLOGY SUITE

USER'S GUIDE

A Comprehensive Guide to Using Verathon Corporation's
Bladder Imaging Technology

VERATHON
MEDICAL

THE SCANPOINT® UROLOGY SUITE

USER'S GUIDE FOR THE BVI 6100, BVI 6200, BVI 6300, BVI 6400 & BVM 6500

VERATHON MEDICAL

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CONTENTS

Welcome 1

Guide Conventions 2

Chapter 1. Getting Started 3

Getting Started with BladderScan® 4
Installing ScanPoint® 4
Connecting the Communication Cradle 8
Removing the ScanPoint Software 8

Chapter 2. Introduction to BladderScan 11

About BladderScan Technology 12
About Measuring Bladder Wall Mass 12
About Measuring Pediatric Bladder Volume 12
BladderScan Components 12
Scanning Unit 13
Charging Cradle 14
Communication Cradle 15
Calibration Targeting System 15
Integrating with ScanPoint 15
Intended Use, Warnings and Cautions 16
Symbol Directory for the Scanning Unit LCD Screen 17

Chapter 3. Measuring Bladder Volume and Bladder Wall Mass 19

Measuring a Patient's Bladder Volume 20
Turning On the Scanning Unit 20
Selecting Gender 20
Applying a Gel Pad 21
Scanning a Patient 21
Recording a Voice Annotation (BVI 6400 Only) 24
Measuring Bladder Wall Mass 24
Using the Bladder Wall Mass Application 24
Turning On the Scanning Unit 25
Downloading the Bladder Wall Mass Application from ScanPoint 25
Determining Bladder Volume and Wall Mass 25

Chapter 4. Assigning the Bladder Monitor (BVI 6300) 29

About Bladder Monitor (BVI 6300) Technology 30
Symbol Directory 30
Assigning and Reassigning the Bladder Monitor 31
Assigning the Bladder Monitor to a New Patient 31
Reassigning the Bladder Monitor to a New Patient 35
Editing and Verifying Patient Information for the Bladder Monitor 37

Measuring Bladder Fullness 40
Turning On the Scanning Unit 40
Applying a Gel Pad 40
Performing a Measurement 40
Transmitting Exam Data to ScanPoint® 42
Verifying Bladder Monitor Patient Information at Return Visit 46
Viewing and Printing Bladder Monitor Exam Results 48
Viewing and Printing New Bladder Monitor Exam Results 48
Viewing and Printing Past Bladder Monitor Exam Results 52
Viewing a Bladder Monitor Assignment List 56

Chapter 5. Using ScanPoint 59

Using ScanPoint 60
About ScanPoint Applications 60
Understanding User Profiles 61
Logging On and Off 61
Transmitting Exam Data to ScanPoint (6100, 6200 & 6500) 63
Transmitting Mobile BladderScan® Exam Data to ScanPoint 68
Viewing and Printing New Exam Results 72
Viewing and Printing the Exam Results for a Specific Patient 75
Viewing Your Account Information 79
Receiving Email Notificaions 83
Online Help 84

Chapter 6. Inspecting and Maintaining BladderScan 85

Cleaning and Disinfecting BladderScan 86
Performing Weekly Inspections 86
Calibrating the Scanning Unit Using ScanPoint 86
Displaying the Days Remaining Until Calibration 86
Using ScanPoint for Calibration 87
Replacing BladderScan 91

Chapter 7. Troubleshooting 93

Troubleshooting Common Problems 94
ScanPoint Error Messages 96

Chapter 8. Contacting Verathon 99

Contacting Verathon Corporation 100
Additional Resources 101

Chapter 9. Product Specifications 103

BladderScan Technical Specifications 104
Compliance With Standards 104
Specifications for the Scanning Unit 104
Accuracy Specification 105
Specifications for the Communication Cradle 106
Specifications for the Charging Cradle 106

ScanPoint® Hardware and Software Requirements 107
Specifications for the Calibration Targeting System 108
Electromagnetic Effects 108
Parts Information 108
Warranty 109
Symbol Directory 110

Appendix A. ScanPoint Legal Information..... 111

Verathon HIPAA Business Associate Agreement..... 112
Health Insurance Portability and Accountability Act (HIPAA)..... 115

Glossary 117

WELCOME

Welcome to the *User's Guide* for Verathon Corporation's Urology Suite. Written for instrument operators, this guide provides comprehensive information about operating and maintaining Verathon's bladder imaging technology. Included in this guide is information regarding:

- **BladderScan® BVI 6100—**Measures bladder volume.
- **Pediatric BladderScan BVI 6200—**Measures pediatric bladder volume.
- **Bladder Monitor (BVI 6300)—**Prosthetic bladder management device.
- **Mobile BladderScan BVI 6400—**Stores multiple, voice-annotated bladder volume exams.
- **BladderScan BVM 6500—**Measures bladder volume and bladder wall mass.
- **ScanPoint® —Verathon**'s online imaging and calibration service.

Collectively, this technology is referred to throughout this guide as "BladderScan and ScanPoint." Organized by subject, this guide contains the following chapters:

Chapter 1: **Getting Started—**Provides set-up information for BladderScan and ScanPoint, including instructions for charging the *scanning unit*, installing ScanPoint software, and connecting the *communication cradle* to your computer.

Chapter 2: **Introduction to BladderScan—**Introduces BladderScan, describes its components in detail, and provides the information needed before using the instrument.

Chapter 3: **Measuring Bladder Volume and Bladder Wall Mass—**Expands upon the information in the Quick Start Guide, providing detailed, step-by-step instructions for measuring the patient's bladder volume and bladder wall mass**.**

Chapter 4: **Assigning the Bladder Monitor (BVI 6300)—**Provides instructions for using the BVI 6300, including information about personalizing the instrument and maintaining patient information.

Chapter 5: **Using ScanPoint—**Offers detailed instructions for using ScanPoint.

Chapter 6: **Inspecting and Maintaining BladderScan—**Provides step-by-step instructions for inspecting and maintaining BladderScan, including how to perform weekly inspections and calibrate the instrument.

Chapter 7: **Troubleshooting—**Answers frequently asked questions and provides solutions to common problems.

Chapter 8: **Contacting Verathon—**Provides comprehensive contact information forVerathon Corporation and lists additional resources.

Chapter 9: **Product Specifications—**Lists the technical specifications of BladderScan. Also includes the product warranty and ordering information.

Appendix A: **ScanPoint Legal Information**—Contains legal documentation for ScanPoint.

Glossary Defines important terminology presented in this *User's Guide*.

Guide Conventions

This *User's Guide* uses the formatting conventions identified in the following table:

Convention	Meaning
Bold	Identifies specific buttons, screens, and user options you will encounter when using the products. For example, a procedure may instruct you to, "Plug the communication cradle's cable into a USB port on your computer and press the instrument's **Scan** button."
Italic	Identifies the names of publications, such as this *Urology Suite User's Guide*, and highlights terms that are defined in the glossary. Italics will also indicate instructions throughout the manual, as when instructing the reader "*To charge the scanning unit*."

CHAPTER 1
GETTING STARTED

This chapter describes the set-up procedures necessary before using BladderScan®. It is important that you read and follow these instructions carefully before using your BladderScan instrument.

In This Chapter

- Getting Started with BladderScan
- Installing ScanPoint®
- Connecting the Communication Cradle
- Removing the ScanPoint Software

Getting Started with BladderScan®

Before using your BladderScan for the first time, and subsequently if your instrument becomes completely discharged, you must charge your scanning unit for six hours, or until it is fully charged.

To charge the scanning unit:

1. Plug the charging cradle into an electrical wall outlet.
2. Place the BladderScan in the charging cradle.

   The battery icon will begin scrolling, indicating that the instrument is charging. If the battery icon does not appear, then your scanning unit was completely discharged and may need to charge for up to six hours. The battery icon will appear when the scanning unit is charged sufficiently for operation.

Note: *If the battery icon with scrolling power segments does not appear after the instrument has been in the cradle for two hours, you need to activate your instrument before continuing to charge. The activation button is located in the opening on the underside of the instrument's handgrip, just above the scan button. Use the tip of the activation tool to press this button and activate your BladderScan. Your instrument is now ready to charge.*

Note: *When you are not using your scanning unit, Verathon Corporation recommends that you store it in the charging cradle to ensure that your instrument is always sufficiently charged. The charging cradle cannot overcharge the battery.*

Installing ScanPoint®

Before using the ScanPoint online service, you must install the required components from the ScanPoint CD-ROM. Your ScanPoint CD-ROM includes:

- **ScanPoint software (required)**
  Allows your scanning unit to communicate with ScanPoint.
- **Shortcuts and desktop icons (optional)**
  Provide links for your Windows® Start menu and desktop that allow you to quickly access ScanPoint, ScanPoint Online Help, and Verathon's home page.
- **ScanPoint Online Help (optional)**
  Describes how to use ScanPoint menus and screens.

Note: *For information about the technical requirements for using ScanPoint, please refer to "Chapter 9. Product Specifications."*

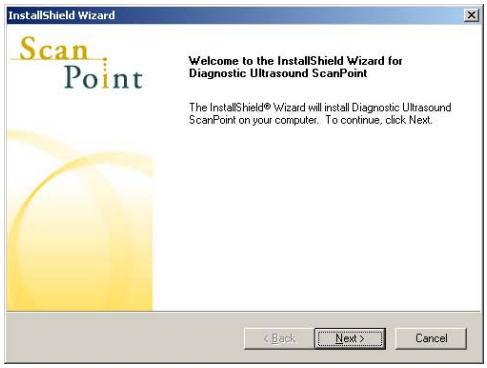
To install ScanPoint:

Note: *You must install the ScanPoint software before connecting the communication cradle to your computer.*

1. Insert the ScanPoint CD-ROM into your computer's CD-ROM drive.

*ScanPoint® displays a **Choose Language Setup** dialog box.*

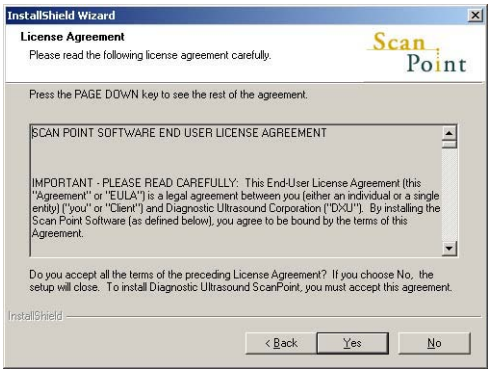
2. From the dropdown list, select your preferred language. To continue, click OK.
   *ScanPoint starts the **InstallShield Wizard** and displays the **Welcome** screen.*


InstallShield Wizard
Scan Point
Welcome to the InstallShield Wizard for Diagnostic Ultrasound ScanPoint
The InstallShield® Wizard will install Diagnostic Ultrasound ScanPoint on your computer. To continue, click Next.
< Back
Next >
Cancel

***Note:** If you do not see the ScanPoint InstallShield installation screen, double-click the **My Computer** icon on your Microsoft® Windows® desktop, and then double-click the icon for your CD-ROM drive.*

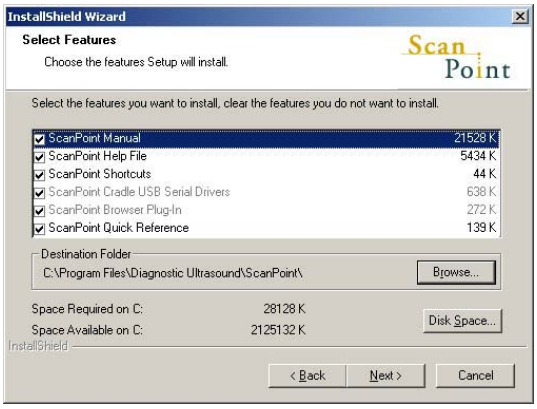
3. To continue and begin the installation, click **Next**.

*ScanPoint® displays the **License Agreement** dialog box.*


InstallShield Wizard
License Agreement
Please read the following license agreement carefully.
Scan Point
Press the PAGE DOWN key to see the rest of the agreement.
SCAN POINT SOFTWARE END USER LICENSE AGREEMENT
IMPORTANT - PLEASE READ CAREFULLY: This End-User License Agreement (this "Agreement" or "EULA") is a legal agreement between you (either an individual or a single entity) ("you" or "Client") and Diagnostic Ultrasound Corporation ("DXU"). By installing the Scan Point Software (as defined below), you agree to be bound by the terms of this Agreement.
Do you accept all the terms of the preceding License Agreement? If you choose No, the setup will close. To install Diagnostic Ultrasound ScanPoint, you must accept this agreement.
InstallShield
< Back
Yes
No

4. Review the contents of the License Agreement. To continue with the installation and accept the terms of the agreement, click **Yes**. If you choose not to accept the terms, you cannot finish installation.

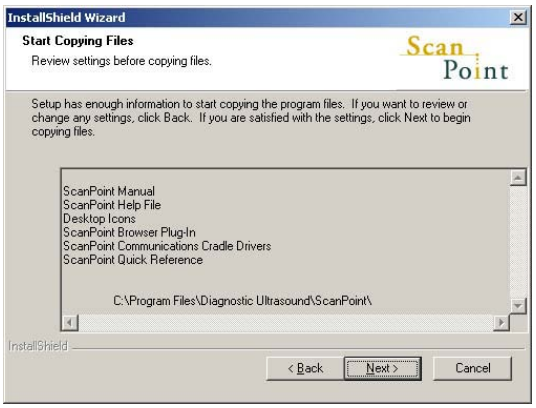
   *ScanPoint displays the **Select Features** dialog box.*


InstallShield Wizard
Select Features
Choose the features Setup will install.
Scan Point
Select the features you want to install, clear the features you do not want to install.
ScanPoint Manual 21528 K
ScanPoint Help File 5434 K
ScanPoint Shortcuts 44 K
ScanPoint Cradle USB Serial Drivers 638 K
ScanPoint Browser Plug-In 272 K
ScanPoint Quick Reference 139 K
Destination Folder
C:\Program Files\Diagnostic Ultrasound\ScanPoint\
Browse...
Space Required on C: 28128 K
Space Available on C: 2125132 K
Disk Space...
InstallShield
< Back
Next >
Cancel

5. Select the components you want to install. If you do not want to save the ScanPoint files to the specified default location, to choose a different location, click the **Browse** button. When completed, to continue, click **Next**.

   ***Note:** The required ScanPoint software components are automatically selected by the Setup Wizard and cannot be deselected. Optional components include Help files and desktop icons. To conserve space on your computer's hard drive you can choose to view ScanPoint Help files directly from the ScanPoint CD-ROM, and you can choose not to install the desktop icons.*

*ScanPoint® displays the **Start Copying Files** dialog box.*

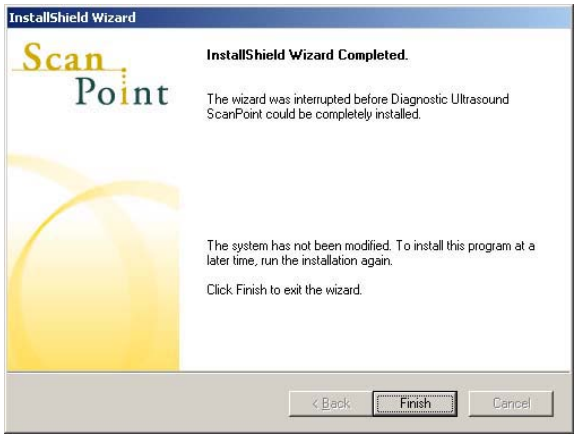

InstallShield Wizard
Start Copying Files
Review settings before copying files.
Scan Point
Setup has enough information to start copying the program files. If you want to review or change any settings, click Back. If you are satisfied with the settings, click Next to begin copying files.
ScanPoint Manual
ScanPoint Help File
Desktop Icons
ScanPoint Browser Plug-In
ScanPoint Communications Cradle Drivers
ScanPoint Quick Reference
C:\Program Files\Diagnostic Ultrasound\ScanPoint\
InstallShield
< Back
Next >
Cancel

6. To begin copying the ScanPoint files, click **Next**.

   *The installation program copies the relevant files from the CD-ROM onto your computer's hard drive. When copying and installation is completed, the installation program displays an **InstallShield Wizard Complete** dialog box.*

7. To finalize your ScanPoint installation, click **Finish**.

8. Remove the ScanPoint CD from your computer's CD-ROM drive.


InstallShield Wizard
Scan Point
InstallShield Wizard Completed.
The wizard was interrupted before Diagnostic Ultrasound ScanPoint could be completely installed.
The system has not been modified. To install this program at a later time, run the installation again.
Click Finish to exit the wizard.
< Back
Finish
Cancel

You have successfully installed ScanPoint onto your computer.

Connecting the Communication Cradle

If your BladderScan® came with a communication cradle, connect this cradle to a USB port on your computer and use it to transmit data to ScanPoint®. When your computer is turned on, you may also use the communication cradle to charge the scanning unit.

Note: *If you shut down the computer connected to your communication cradle, no power will be transmitted to the scanning unit via the communication cradle, and the instrument will not continue to charge.*

Note: *You must install the ScanPoint software before connecting the communication cradle to your computer.*

To connect the communication cradle:

1. Turn your computer off.
2. Plug the communication cradle's cable into a USB port on your computer.
3. Turn your computer back on.

   If the communication cradle is connected to your computer correctly, the green power light on the cradle lights up.

4. Place the scanning unit in the cradle, fitting the notch into the base of the scanning unit onto the matching peg on the communication cradle.
5. If you did not install the ScanPoint software from the ScanPoint CD-ROM, ScanPoint prompts you to install it now. To install the ScanPoint software, click **Yes** and follow the instructions in the *Installing ScanPoint* section of this manual.

   Note: *If you do not install the ScanPoint software, your scanning unit cannot communicate with ScanPoint.*

Important: *Your computer must be minimally certified to EN/IEC / CSA / UL 950 or 60101-1 standards. This configuration ensures that compliance to the EN/IEC 60601-1-1 system standard is maintained. Any person who connects additional equipment to the signal input port or signal output port configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard EN/IEC 60601-1-1. If you need assistance, contact Verathon's Customer Service department or your local representative.*

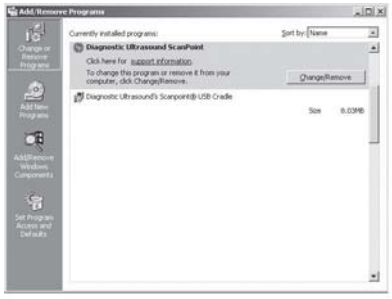
Removing the ScanPoint Software

If necessary, you can remove the ScanPoint software. If you choose to remove the software, you must reinstall it before you can transmit exam data to ScanPoint and calibrate the scanning unit.

To remove ScanPoint in a Microsoft Windows® operating system:

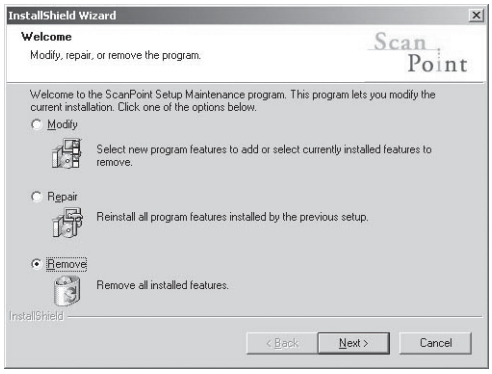
1. Click the **Start** button, and then open Control Panel.
2. Locate and double-click the **Add/Remove Programs** icon.

*ScanPoint® displays the **Add/Remove Programs** dialog box.*



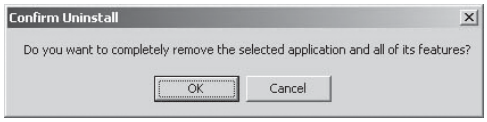
3. In the **Currently Installed Programs** list, locate and select **Verathon ScanPoint**, and then click the **Change/Remove** button.

   *ScanPoint displays the **InstallShield Wizard** dialog box.*


InstallShield Wizard
Welcome
Modify, repair, or remove the program.
Scan Point
Welcome to the ScanPoint Setup Maintenance program. This program lets you modify the current installation. Click one of the options below.
Modify
Select new program features to add or select currently installed features to remove.
Repair
Reinstall all program features installed by the previous setup.
Remove
Remove all installed features.
InstallShield
< Back
Next >
Cancel

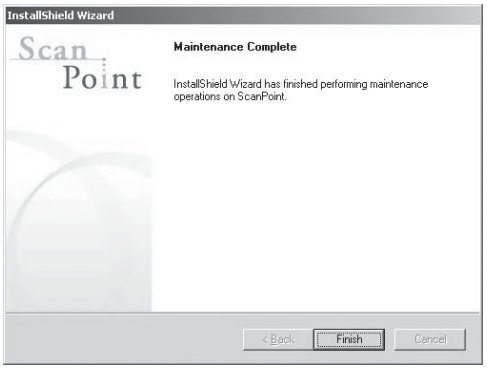
4. Click the **Remove** option button. To continue, click **Next**.

   *ScanPoint displays a **Confirm Uninstall** dialog box.*



5. To confirm and continue the uninstall program, click **OK**.

   *ScanPoint® displays the **Maintenance Complete** dialog box.*



6. To finalize the uninstall, click **Finish**.

   *The **InstallShield Wizard** removes the ScanPoint software from your system.*

CHAPTER 2
INTRODUCTION TO BLADDERSCAN®

This chapter provides an overview of Verathon Corporation's bladder imaging technology. Read this section to learn about the intended use and components of BladderScan and how the instrument integrates with ScanPoint®. Before operating BladderScan, you should also read the important safety notices contained in this chapter.

In This Chapter

- About BladderScan Technology
- About Measuring Bladder Wall Mass
- About Measuring Pediatric Bladder Volume
- BladderScan Components
- Integrating with ScanPoint
- Intended Use, Warnings and Cautions
- Symbol Directory for the Scanning Unit LCD Screen

About BladderScan® Technology

BladderScan is a portable, battery-operated V-MODE® ultrasonic instrument that is intended for the noninvasive measurement of urinary bladder volume and bladder wall mass on an intermittent basis. During each scan, BladderScan employs patented V-MODE technology to obtain multiple, consecutive B-mode images and create a three-dimensional image of the bladder. BladderScan automatically calculates and displays measurements based upon this image, to provide the greatest ease of use. V-MODE measurements tend to be more accurate than those obtained from conventional two-dimensional ultrasound, as they are based on a more complete, multi-faceted image.

About Measuring Bladder Wall Mass

Users who have purchased the BladderScan BVM 6500 can calculate both bladder wall mass and bladder volume. With the BVM 6500 and ScanPoint®, bladder wall mass can be measured quickly and noninvasively.

About Measuring Pediatric Bladder Volume

Intended for use on children up to 48 inches tall and weighing 60 pounds or less, Pediatric BladderScan measures bladder volumes within the range of 0-200 ml. Instructions and information about measuring bladder volume in this *User's Guide* apply to both the BladderScan and Pediatric BladderScan instruments.

BladderScan Components

Your BladderScan may include some or all of the following components:

- Scanning unit
- Charging cradle
- Communication cradle
- Calibration targeting system

You'll find more information about each of these components on the following pages.

Scanning Unit

Use the handheld scanning unit to measure a patient's bladder volume or bladder wall mass. The scanning unit produces an ultrasound image of the bladder and determines bladder volume and/or mass based on that image. The features of the scanning unit include:

Component	Description
Scanhead	Rounded dome is the surface through which ultrasound waves are transmitted.
LCD (liquid-crystal display) screen	Displays the bladder volume measurement and other scan, patient, and instrument data. (For more information, see the symbol directory at the end of this chapter.)
Top (Gender) button	Located just below the LCD screen.
Scan button	To begin bladder imaging, press this button, located on the underside of the handgrip.
Activation button	Located in the small opening on the underside of the scanning unit's handgrip (above the Scan button), use the activation tool to press this button to reactivate your scanning unit when the battery is completely discharged.
Infrared (IR) window	Located at the base of the handgrip, this window enables the scanning unit to communicate with your computer via the communication cradle.
Labeling	Located below the Scan button, you'll find the label with your instrument's name, product and serial numbers, and classifications.
Microphone	Located above the LCD screen on the BVI 6400 instrument only. Speak into the microphone to record a voice annotation following patient exams.

Charging Cradle

Use the charging cradle to charge the scanning unit's battery. The charging cradle plugs directly into an electrical wall outlet. Before using your scanning unit, you must charge it for six hours.

Reading the Battery Power Status

The battery icon is located in the lower-right corner of the scanning unit's LCD screen. When the scanning unit is not charging, this icon indicates the power level of the battery. At a minimum, you should recharge the scanning unit whenever you see a single power segment remaining in the battery icon. While charging, the battery icon displays scrolling power segments.

The following table describes how to read the battery icon.

Battery Icon	Status	Description
	100%	Four power segments indicate that the battery is fully charged and ready for use.
	75%	Three power segments indicate a partially discharged battery.
	50%	Two power segments indicate a partially discharged battery.
	25%	One power segment indicates that the battery is nearly discharged. You will be able to perform a few more scans, but should recharge the battery soon.
	0%	An empty battery icon (no power segments) indicates that the battery is completely discharged. The scanning unit will not work.
	Scrolling	Indicates that the instrument is being charged.

Communication Cradle

Use the communication cradle to transmit calibration and exam data to ScanPoint®. The cradle's cable plugs directly into a Universal Serial Bus (USB) port on your personal computer. You can also charge your scanning unit in the communication cradle while transmitting data to and from ScanPoint.

Calibration Targeting System

Use the calibration targeting system in conjunction with ScanPoint to calibrate your instrument for maximum accuracy. The calibration targeting system consists of a spiral-shaped calibration target located within a specially designed calibration container. For more information about calibration, see *"Chapter 6. Inspecting and Maintaining BladderScan®,"* in this *User's Guide*.

Integrating with ScanPoint

Verathon's ScanPoint is an online service that enhances and expands the capabilities of BladderScan. ScanPoint is included as part of your Total Reliability Plan℠.

You can use ScanPoint to:

- Save exam data
- View ultrasound images from exams
- Print exam results
- Determine bladder wall mass measurements with the BVM 6500
- Assign the BVI 6300 scanning unit to a patient and view exam data
- Calibrate your BladderScan instrument
- Access your account and payment information

Note: *ScanPoint meets all the patient data privacy requirements of HIPAA*. ScanPoint uses the Secure Sockets Layer (SSL) protocol to insure the confidentiality of exam records as they are transmitted over the Internet.*

****Health Insurance Portability and Accountability Act***

Note: *To use ScanPoint, you must have Windows® 2000 and Microsoft® Internet Explorer version 6.0 or later installed on your computer. For more detailed information about using ScanPoint, see "Chapter 5. Using ScanPoint," in this User's Guide.*

Intended Use, Warnings and Cautions

BladderScan® should be used only by individuals who have been trained and authorized by a physician or by the institution providing care for the patient. All operators must read this entire *Urology Suite User's Guide* prior to using BladderScan. Do not attempt to operate the instrument until you thoroughly understand all instructions and procedures in this *User's Guide*. Failure to comply with instructions may compromise the performance of the instrument.

Statement of Prescription:	United States Federal law restricts BladderScan to use by, or on the order of, a physician. This statement is required per 21 Code of Federal Regulations (CFR) 801.109. *Note: It is standard practice to have medical staff authorize the use of medical equipment to be used within its intended use throughout the institution. Individual prescriptions for use are not required.*
Statement of Intended Use:	BladderScan projects ultrasound energy through the lower abdomen of the non-pregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume and/or bladder wall mass noninvasively.
Contraindication:	BladderScan is contraindicated for fetal use and for use on pregnant patients.
Warning:	If you use BladderScan in the presence of flammable anesthetics, the hazard of potential explosion exists.
Warning:	To date, exposure to low power, pulsed Verathon has not been shown to produce adverse effects. However, medical professionals should use ultrasound only when clinically indicated, using the lowest exposure times possible commensurate with clinical utility. The ultrasonic output power of BladderScan is not user adjustable and is limited to the minimum level necessary for effective performance. For more information about acoustic output levels, see "Chapter 9. Product Specifications," in this *User's Guide*.
Caution:	When using BladderScan, be aware of the following conditions, which can affect ultrasound transmission and decrease the accuracy of exam results: ▪ Use care when scanning patients who have had *supra-pubic* or pelvic surgery. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection. ▪ Do not use the scanning unit on a patient with open skin or wounds in the *supra-pubic* region. ▪ If you scan a patient with a catheter in his or her bladder, the catheter may affect measurement accuracy; however, the information so obtained has clinical utility (e.g. detection of a blocked catheter).

Symbol Directory for the Scanning Unit LCD Screen: BVI 6100, BVI 6200, BVI 6400, BVM 6500

The symbols shown in the table may appear on the scanning unit's LCD screen for the following instruments:

- BVI 6100
- BVI 6200
- BVI 6400
- BVM 6500

Note: *For a symbol directory for the BVI 6300, refer to "Chapter 4. Assigning the Bladder Monitor (BVI 6300)."*

Symbol	Description
	Indicates days remaining until calibration
	Battery power level
	Female option selected
	Bladder imaging in progress (BVI 6100, BVI 6200, BVI 6400, BVM 6500)
	Flashing arrows indicate you must re-aim the scanning unit in the direction of the arrows after the scan attempt. If the arrow is solid, re-aiming is optional.
	Indicates that true bladder volume is greater than displayed volume.
	(BVI 6400 only) Indicates that voice annotation is being recorded and stored.

CHAPTER 3
MEASURING BLADDER VOLUME AND BLADDER WALL MASS

This chapter provides detailed, step-by-step instructions for measuring bladder volume and bladder wall mass.

In This Chapter

- Measuring a Patient's Bladder Volume (Adult, Pediatric)
- Measuring a Patient's Bladder Wall Mass

Measuring a Patient's Bladder Volume

The following section describes how to measure a patient's bladder volume with BladderScan®. Before you begin the exam, make sure that you clean and disinfect the scanning unit to minimize the risk of infection.

If you are a new instrument operator, Verathon recommends that you use BladderScan on a patient with a moderately full bladder, rather than initially attempting to locate and scan a nearly empty bladder.

Turning On the Scanning Unit

If you have stored your scanning unit in the charging cradle or the communication cradle, the power will be on when you remove it from the cradle. If the scanning unit is not stored in the cradle, it goes into *sleep mode* when not in use, and you must turn it on before measuring bladder volume.

To turn on the scanning unit:

1. If the scanning unit is in sleep mode, press and release any button. When the scanning unit chirps, it is ready to scan.

   Note: *If it does not turn on, the battery may be completely discharged. For more information, see "Chapter 2, Introduction to BladderScan."*

2. Check the battery icon to verify that the battery is sufficiently charged for patient exams. If the battery icon shows no power segments, return the scanning unit to the charging cradle and recharge it before attempting to perform exams. If the battery icon shows only one power segment, you can perform a few more scans but you will need to recharge your instrument soon. For more information about charging the scanning unit, see *"Chapter 1. Getting Started,"* in this *User's Guide*.

Selecting Gender

In order to obtain an accurate bladder volume measurement, you must first select the appropriate gender. Gender selection allows the scanning unit to take into account the presence or absence of a uterus when calculating bladder volume.

To select the patient's gender:

1. Press the **Top (Gender) button**, located below the LCD screen:
   - Select the female option if the patient is a female who has not undergone a hysterectomy. The female option allows BladderScan to exclude the uterus, which may resemble the bladder ultrasonically. When the female option is selected, a female icon will appear on the scanning unit's LCD screen.
   - If the patient is a male, or a female who has undergone a hysterectomy, press the **Top (Gender) button** to toggle between options until the gender icon no longer appears on the LCD screen.

Applying a Gel Pad

To apply a gel pad and scan the patient:

1. Clean and disinfect the scanhead of the scanning unit by wiping it gently with a germicidal wipe or a soft cloth soaked in isopropyl alcohol. For more information about cleaning and disinfecting BladderScan®, see *"Chapter 6. Inspecting and Maintaining BladderScan."*
2. Prepare to apply a Sontac® ultrasound gel pad by peeling back the foil lid of the individual Sontac packaging to expose the gel pad. To avoid patient cross-contamination, use a new gel pad for each patient.
3. With the patient resting quietly in the supine position, palpate the symphysis pubis.
4. Place the gel pad midline on the patient's abdomen, approximately 1 inch (3 cm) above the symphysis pubis.

Scanning a Patient

When using BladderScan, be aware of the following conditions, which may affect ultrasound transmission and the accuracy of your exam results:

- When scanning a patient with a catheter in his or her bladder, the catheter may affect the accuracy of the resulting bladder volume measurement; however, measurements so obtained are still clinically useful (i.e., detecting a blocked catheter).
- Do not use the scanning unit on a patient with open skin or wounds in the *supra-pubic* region.
- Use care when you scan patients who have had *supra-pubic* or pelvic surgery. Scar tissue, surgical incisions, sutures, and staples can affect ultrasound transmission and reflection.

To scan the patient:

1. Place the scanhead on the gel pad, aimed slightly downward toward the expected location of the bladder. For most patients this means aiming the tip of the scanhead toward the patient's coccyx (tailbone).

Note: *We recommend that you place the scanning unit so that the right-hand side of the LCD screen is oriented toward the patient's feet. This will ensure that when you view ultrasound images on ScanPoint®, the orientation of the images will be properly identified.*

2. Press and release the **Scan** button, located on the underside of the scanning unit's handgrip.

   After a scan, the LCD screen displays some or all of the following information:

- **Measured bladder volume**
  The volume measurement in milliliters (ml) appears in large type in the top half of the screen.

- **Aiming arrows**
  Located in the bottom center of the screen, these arrows identify the location of the bladder relative to the scanhead. If the scanning unit was aimed properly, so that the bladder was centered within the *image cone*, the aiming arrows will either not appear, or will not flash.

3. If the aiming arrows are flashing, you must re-aim the scanning unit and perform the exam again. Aim the scanning unit in the direction indicated by the arrows, and press the **Scan** button again. For example, if the LCD screen displays a flashing arrow pointing to the left, the bladder is located to the left of the scanhead. Without lifting the scanning unit, tilt it so it projects ultrasound further to the left. Repeat this step until the arrows no longer flash.

   Note: *If solid aiming arrows appear, then re-aiming is not required. A solid arrow indicates that the bladder is not completely centered in the image cone, but the measurement is still clinically useful. If desired, re-aim the scanning unit and re-scan the patient as described above. For patients with bladders that are oblong or extremely large, a solid arrow may accompany good measurements.*

4. To secure the highest degree of accuracy, Verathon Corporation recommends that you scan the patient's bladder at least three times per exam, to ensure the repeatability of your measurements. Repeat Steps 1-3 to scan the bladder again.

   Note: *Repeatability refers to your ability to center the bladder during each measurement, not your ability to obtain exactly the same bladder volume measurement each time. Volume measurements should be close, but need not be identical. If you cannot obtain an optimal, repeatable measurement, the accuracy of the result is compromised.*

   Important: *The accuracy of your measurement depends on properly aiming the scanning unit. Errors in usage typically result in the underestimation of bladder volume, except when the scanning unit is moved during the scan. In this case, the measurement may overestimate the actual bladder volume. The presence of a catheter in the patient's bladder can also affect the accuracy of scan results by overestimating bladder volume.*

5. When you are satisfied that the scanning unit was aimed properly and the scan result is accurate, note the bladder volume measurement displayed on the LCD screen.

   Note: *If you are using the BladderScan® models BVI 6100, BVI 6200, or BVM 6500 to determine bladder volume, you may want to chart this measurement, because the scanning unit will not save it after you begin a new exam. If desired, you can also view, save and print exam results using ScanPoint®. See "Chapter 5. Using ScanPoint" for more information. If you are using the BVI 6400, you can save the measurement in the scanner's memory by recording a voice annotation. See the following section, titled, "Recording a Voice Annotation" for details.*

   Important: *If you do not return the scanning unit to the charging cradle or communication cradle within 20 minutes of completing the exam, the scanning unit will go into sleep mode to conserve battery power. Unless saved by using ScanPoint, or by recording a voice annotation (BVI 6400), bladder imaging data will be lost when the scanning unit goes into sleep mode.*

Bladder	Example Display	Displayed
Optimal Scan of Patient's Bladder		
Bladder is contained		Volume displayed No > symbol No arrow or solid arrow
Bladder is contained Bladder volume is greater than 999 ml		Volume displayed is 999 ml > symbol
Bladder is partially contained Bladder volume is too high to be fully contained within scan cone		Volume is displayed > symbol Flashing arrow or no arrow
Optional Rescan		
Bladder is partially contained within scan cones		Volume displayed Solid arrow in direction of optional rescan
Rescan Patient's Bladder		
Bladder partially contained		Volume displayed Flashing arrow in direction to rescan

Recording a Voice Annotation (BVI 6400 Only)

When you complete a bladder volume exam with the Mobile BladderScan® BVI 6400, you can record a voice annotation to be saved with the exam. The voice annotation is replayed when the exam is viewed on ScanPoint®. The BVI 6400 holds ten or more patient exams at once, so the operator can download multiple exams to ScanPoint in one sitting. The voice annotation associated with each exam ensures that important patient and exam data is retained.

To record a voice annotation:

1. Follow the instructions for measuring bladder volume, above.
2. Press and hold the **Top button** until you hear a tone (approx. 3 seconds).
3. Record your message. Speak into the microphone, located above the instrument's LCD screen.

   Note: Continue holding the top button while recording your voice annotation. Be sure to include all relevant exam information, including the patient's name and your name (name of the person performing the exam).
4. Release the top button and listen as your voice annotation is replayed. If you are not satisfied with the annotation, press and hold the top button to record a new message (return to step 1, above). If you are satisfied with the annotation, do not press any buttons. After several seconds, the instrument automatically accepts and stores the annotation with the exam. The microphone icon on the LCD screen flashes while the exam and voice annotation are being saved.
5. You may now begin a new patient exam, if desired.

Measuring Bladder Wall Mass

When used in conjunction with ScanPoint, the BladderScan BVM 6500 measures both bladder volume and bladder wall mass. Please note that the measurement displayed on your scanning unit will be a bladder ***volume*** measurement; ScanPoint will generate your bladder ***wall mass*** measurement after you have uploaded your exam information. You can view the bladder wall mass measurement in ScanPoint on the Bladder Wall Mass **Exam Results** page.

The following section describes how to measure a patient's bladder wall mass with the BladderScan BVM 6500. Before you begin the exam, make sure that you clean and disinfect the scanning unit to minimize the risk of infection.

Using the Bladder Wall Mass Application

There are three main parts to the bladder wall mass procedure:

- Download the bladder wall mass application from ScanPoint
- Scan the patient and determine if bladder volume is sufficient for a bladder wall mass exam (bladder volume must be between 200 and 400 ml)
- Use ScanPoint to view the bladder wall mass measurement

Turning On the Scanning Unit

If you have stored your scanning unit in the charging cradle or communication cradle, the power will be on when you remove it from the cradle. If the scanning unit is not stored in the cradle, it goes into *sleep mode* when not in use, and you must turn it on before measuring bladder volume.

To turn on the scanning unit:

1. If the scanning unit is in sleep mode, press and release any button. When the scanning unit chirps, it is ready to scan.

   Note: *If the scanning unit does not turn on, the battery may be completely discharged. For more information, see "Chapter 2. Introduction to BladderScan®."*

2. Check the battery icon to verify that the battery is sufficiently charged for patient exams. If the battery icon shows no power segments, return the scanning unit to the charging cradle and recharge it before attempting to scan a patient. If the battery icon shows only one power segment, you can perform a few more scans but you will need to recharge your instrument soon. For more information about charging the scanning unit, see *"Chapter 1. Getting Started,"* in this *User's Guide*.

Downloading the Bladder Wall Mass Application from ScanPoint®

Before taking a measurement, you will need to download the Bladder Wall Mass application from ScanPoint.

To download the Bladder Wall Mass application from ScanPoint:

1. Place the scanning unit in the communication cradle, which should be connected to your computer.
2. Go to the ScanPoint website by double-clicking the **ScanPoint** icon on your Windows® desktop, or by opening Internet Explorer and typing **https://my.scanpoint.com/** in the browser's address bar.
3. Log on to ScanPoint by typing your **Login Name** and **Password** on the **Sign in** screen and then clicking the **Sign in** button.
4. Follow the steps in ScanPoint for downloading the Bladder Wall Mass application.

Determining Bladder Volume and Wall Mass

Note: *Bladder volume must be between 200 and 400 ml to obtain an accurate bladder wall mass measurement.*

Selecting Gender

In order to obtain an accurate measurement, you must first select the appropriate gender. Gender selection allows the scanning unit to take into account the presence or absence of a uterus when calculating bladder volume.

To select the patient's gender:

1. Press the **Top (Gender) button**, located below the LCD screen:

   - Select the female option if the patient is a female who has NOT undergone a hysterectomy. The female option allows BladderScan to exclude the uterus, which may resemble the bladder

ultrasonically. When the female option is selected, a female icon will appear on the scanning unit's LCD screen.

- If the patient is a male, or a female who has undergone a hysterectomy, press the **Top (Gender) button** to toggle between options until the gender icon no longer appears on the LCD screen.

Applying a Gel Pad

To apply a gel pad and scan the patient:

1. Clean and disinfect the scanhead of the scanning unit by wiping it gently with a germicidal wipe or a soft cloth soaked in isopropyl alcohol. For more information about cleaning and disinfecting BladderScan®, see *"Chapter 6. Inspecting and Maintaining BladderScan."*
2. Prepare to apply a Sontac® Ultrasound gel pad by peeling back the foil lid of the individual Sontac packaging to expose the gel pad. To avoid patient cross-contamination, use a new gel pad for each patient.
3. With the patient resting quietly in the *supine* position, palpate the *symphysis pubis*.
4. Place the gel pad midline on the patient's abdomen, approximately 1 inch (3 cm) above the *symphysis pubis.*

Scanning a Patient

Note: *Bladder volume must be between 200 and 400 ml to obtain an accurate bladder wall mass measurement.*

1. Place the scanhead on the gel pad, angled slightly downward toward the expected location of the bladder. For most patients, this means aiming the tip of the scanhead towards the coccyx (tailbone).

   Note: *We recommend that you place the scanning unit so that the right-hand side of the LCD screen is oriented toward the patient's feet. This will ensure that when you view ultrasound images on ScanPoint®, the orientation of the images will be properly identified.*

2. Press and release the **Scan** button located on the underside of the scanning unit's handgrip. To help ensure accurate imaging, hold the scanning unit steady until the scan is complete. Avoid changing its position, angle, or pressure.

After a scan, your scanning unit's LCD screen displays some or all of the following information:

- **Measured bladder volume**
  The volume measurement in milliliters (ml) appears in large type in the top half of the screen.
- **Aiming arrows**
  Located in the bottom center of the screen, these arrows identify the location of the bladder relative to the scanhead. If the scanning unit was aimed properly so that the bladder was centered within the *image cone*, the aiming arrows will not flash.

3. If the aiming arrows are flashing, you must re-aim the scanning unit and perform the exam again. Aim the scanning unit in the direction indicated by the arrows and press the **Scan** button again. For example, if the LCD screen displays a flashing arrow pointing to the left, the bladder is located to the left of the scanhead. Without lifting the scanning unit, tilt it so it projects ultrasound further to the left. Repeat this step until the arrows no longer flash.

Note: *If solid aiming arrows appear, then re-aiming is not required. A solid arrow indicates that the bladder is not completely centered in the image cone, but the measurement is still clinically useful. If desired, re-aim the scanning unit and re-scan the patient as described above. For patients with bladders that are oblong or extremely large, a solid arrow may accompany good measurements.*

4. To secure the highest degree of accuracy, Verathon Corporation recommends that you scan the patient's bladder at least three times, to ensure the *repeatability* of your measurements. Repeat Steps 1-3 to scan the bladder again.

   Note: *Repeatability refers to your ability to center the bladder during each measurement, not your ability to obtain exactly the same bladder volume measurement each time. Volume measurements should be close, but need not be identical. If you cannot obtain an optimal, repeatable measurement, the accuracy of the result is compromised.*

5. When you are satisfied that the scanning unit was aimed properly and the scan result is accurate, note the bladder volume measurement displayed on the LCD screen.

   Important: *If you do not return the scanning unit to the charging cradle or communication cradle within 20 minutes of completing the exam, the scanning unit will go into sleep mode to conserve battery power. Measurement data will be lost when the scanning unit goes into sleep mode.*

6. Verify that the bladder volume measurement is sufficient for a bladder wall mass exam. In order to obtain an accurate bladder wall mass measurement, the measured bladder volume must be between 200 and 400 milliliters.

7. Use ScanPoint® to view bladder wall mass results.

   - Place the scanning unit in the communication cradle, and log on to ScanPoint.
   - Click **Bladder Wall Mass**
   - Verify Patient Information
   - Click **Transmit Exam**

   Note: *ScanPoint uploads and analyzes your exam data. This can take several minutes.*

8. At the bottom of the page, click the option, **Click Here to View Your Exam Results**.

   Your exam results will appear, including scan and patient information, bladder volume and wall mass measurements, and ultrasound images. If desired, you may print the exam results and ultrasound images.

CHAPTER 4
ASSIGNING THE BLADDER MONITOR (BVI 6300)

Intended for use on adult or pediatric patients with neurogenic or overactive bladders, the Bladder Monitor (BVI 6300) enables healthcare providers to prescribe BladderScan® for individual use, allowing patients to monitor their own bladder volume levels.

The Bladder Monitor looks like other BladderScan instruments, but can be used by both healthcare providers and patients. Healthcare providers can program the Bladder Monitor for the patient, specifying gender, target bladder volume, and whether the patient is pediatric or adult. If desired, the healthcare provider can also specify the date that a patient should return to have their exam data analyzed and patient information updated.

This chapter describes the procedures that the healthcare provider can use when instructing patients in self-use of the Bladder Monitor.

In This Chapter

- About Bladder Monitor Technology
- Symbol Directory
- Assigning and Reassigning the Bladder Monitor
- Measuring Bladder Fullness
- Transmitting Exam Data
- Verifying Bladder Monitor Patient Information at Return Visit
- Viewing and Printing Bladder Monitor Exam Results
- Viewing a Bladder Monitor Assignment List

About Bladder Monitor (BVI 6300) Technology

The Bladder Monitor (BVI 6300) allows healthcare providers to personalize BladderScan® so patients can monitor their own bladder volume levels. Using the Bladder Monitor, you may specify gender, target bladder volume, and whether the patient is pediatric or adult, and you have the option to set the required return exam date (when the patient should return to have his patient information analyzed and updated).

The Bladder Monitor looks like other BladderScan instruments, but it can be used by both healthcare providers and patients. This section was written to help the healthcare provider instruct patients in self-use of the Bladder Monitor BVI 6300.

Symbol Directory

Symbols on the Bladder Monitor LCD screen differ from the symbols on other BladderScan scanning units. The following symbols may appear on the Bladder Monitor LCD screen:

Symbol	Description
	Displays level of bladder fullness.
	Located on all four sides of the screen, these arrows identify the location of the bladder relative to the scanhead. If the scanning unit was aimed properly, so that the bladder was contained within the image cone, the aiming arrows will either not appear, or will not flash.
	Flashing arrows mean you must re-aim the scanning unit in the direction indicated by the arrows. If the arrow is not flashing, re-aiming is optional.
	Pre-void measurement.
	Post-void measurement.
	Patient is reminded that a visit is due with their healthcare provider. After patient exam data is uploaded to ScanPoint® for review, the healthcare provider must verify that the patient profile is accurate. If the profile is not verified and uploaded to the instrument, this symbol will flash and the Bladder Monitor will not perform exams.
	When this icon begins to scroll, the scanning unit must be calibrated within 30 days in order to maintain functionality.
	When this icon begins to flash, the scanning unit must be calibrated before another scan can be completed.
	When this icon is solid (i.e., not flashing or scrolling), bladder imaging is in progress.

Assigning and Reassigning the Bladder Monitor

Healthcare providers may use ScanPoint® to personalize the Bladder Monitor. ScanPoint enables the specification of gender, target bladder volume, whether the patient is pediatric or adult, and the date that a patient should return to have his exam data analyzed (optional).

This section describes how to:

- Assign a Bladder Monitor to a patient
- Reassign a Bladder Monitor to a new patient
- Edit and verify patient information

Assigning the Bladder Monitor to a New Patient

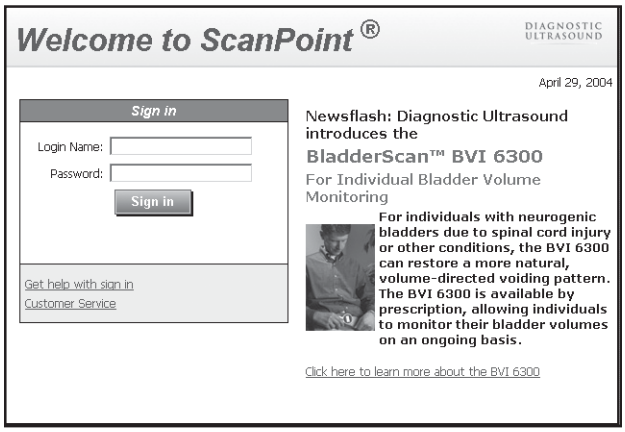
When ScanPoint displays the **Bladder Monitor Patient Information** screen, all of the data fields are empty until you enter the relevant information and assign the unit. The following procedure describes how to assign a new scanning unit to a new patient.

To assign the Bladder Monitor to a new patient:

1. Place the scanning unit in the communication cradle, which must be connected to your computer. ScanPoint software must also be installed.
2. If you did not install the ScanPoint software from the ScanPoint CD-ROM, ScanPoint prompts you to install it now. To install the ScanPoint software, click **Yes**.

   Note: *If you do not install the ScanPoint software, your scanning unit cannot communicate with ScanPoint, and you will not be able to configure the Bladder Monitor for patient use.*
3. Go to the ScanPoint website at **https://my.scanpoint.com**, or double-click the **ScanPoint** icon installed on your desktop.

   ScanPoint displays the ***Sign In*** *screen.*


Welcome to ScanPoint ®
DIAGNOSTIC ULTRASOUND
April 29, 2004
Sign in
Login Name:
Password:
Sign in
Get help with sign in
Customer Service
Newsflash: Diagnostic Ultrasound introduces the
BladderScan™ BVI 6300
For Individual Bladder Volume Monitoring
For individuals with neurogenic bladders due to spinal cord injury or other conditions, the BVI 6300 can restore a more natural, volume-directed voiding pattern. The BVI 6300 is available by prescription, allowing individuals to monitor their bladder volumes on an ongoing basis.
Click here to learn more about the BVI 6300

Field	Action
Login Name	Type the Username that Verathon Corporation assigned to you for logging on to ScanPoint®.
Password	Type the secure password that Verathon Corporation assigned to you for logging on to ScanPoint.
Sign In	Click here to log on to ScanPoint.
Get help with sign in	Click here to get help.

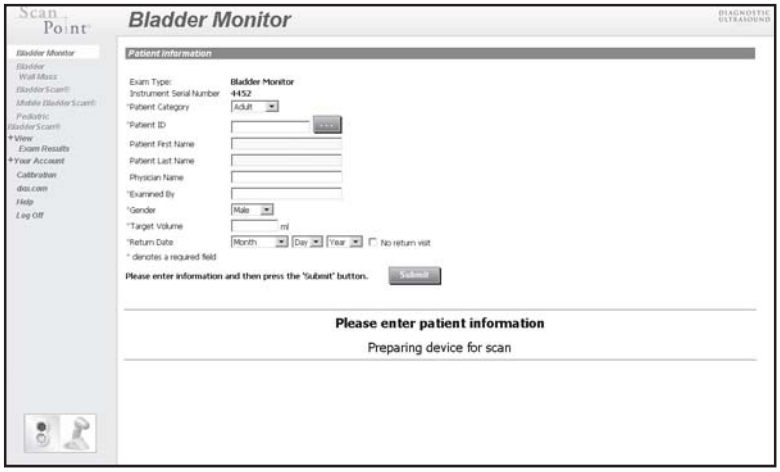
4. To log on to ScanPoint, on the **Sign In** screen, type values for the following fields.

   - **Login Name**
     The username that Verathon Corporation assigned to you for logging onto ScanPoint.
   - **Password**
     The password that Verathon Corporation assigned to you for logging onto ScanPoint.

5. Click the **Sign in** button. ScanPoint validates your username and password and starts a secure session (identified by the yellow padlock symbol at the lower right-hand corner of the browser window).

6. On the ScanPoint menu, click **Bladder Monitor**.

   *ScanPoint displays the **Bladder Monitor Patient Information** screen with empty data fields. If the data fields are not empty and contain information, the scanning unit that you are assigning was previously assigned to another patient. You may overwrite this information if needed.*



Field	Description
Serial Number/Exam Type	Displays the instrument serial number and the type of scanning unit.
Patient Category*	Select the exam type that meets one of the following criteria. • Adult (height ≥ 49 in; weight ≥ 61 lbs) • Pediatric (height ≤ 48 in; weight ≤ 60 lbs)
Patient ID*	Type the Patient ID.
Patient First Name	Type the patient's first name.
Patient Last Name	Type the patient's last name.
Physician Name	Type the name of the physician who has prescribed the instrument.
Examined By*	Type the name of the person who will perform the exams.
Gender*	Select the appropriate gender from the drop-down list.
Target Volume*	Specify the target volume that corresponds to the patient being assigned the instrument. The target volume is the volume at which the patient should void or perform catheterization.
Return Date*	Select the date that the patient should return for a follow-up consultation.
No return visit	Select the check box if no return visit is scheduled or planned.
Submit	Click here to submit the data and finalize the assignment of the unit to the patient.
Status Box	Review additional messages, instructions, and the status of your actions here.

7. In the **Patient Profile** section of the screen, type values for each of the following fields.
   Note: *You must type information in all fields marked with a red asterisk (*).*

   - **Patient Category***

     Use the drop-down menu to select one of the following exam types:

     - ***Adult*** (height ≥ 49 in; weight ≥ 61 lbs)

     - ***Pediatric*** (height ≤ 48 in; weight ≤ 60 lbs)

   - **Patient ID***

     Type the identification value, which can be any combination of numbers, letters, or other characters that you have assigned to the patient in ScanPoint®. If you cannot remember the **Patient ID** for an existing patient, click the **Lookup** button, located to the right of the **Patient ID** field.

   - **Patient First Name**

     Type the patient's first name.

   - **Patient Last Name**

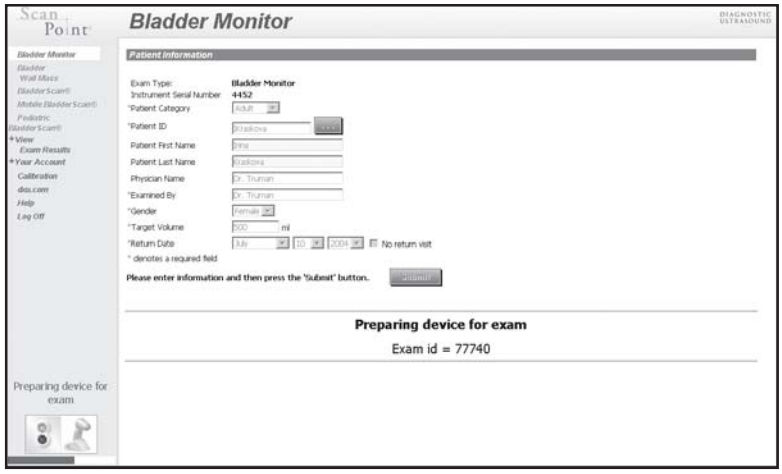
     Type the patient's last name. If you used the **Lookup** feature to locate the Patient ID, ScanPoint automatically displays the correct patient name, and his or her information will appear in the Patient Profile section of the screen.

- **Physician Name**
  Type the name of the physician who has prescribed the instrument.
- **Examined By***
  Type the name of the person who will perform the exams.
- **Gender***
  In the drop-down list, select male or female.
  Note: For female patients who have had a hysterectomy, select **Male**.
- **Target Volume***
  Type the numerical value (in ml) for the patient's target volume, which is the volume at which the patient should void or perform catheterization.
- **Return Date***
  Use the drop-down menu to specify the date that the patient should return for a follow-up consultation. If no return visit is scheduled or planned, select the no return visit check box.

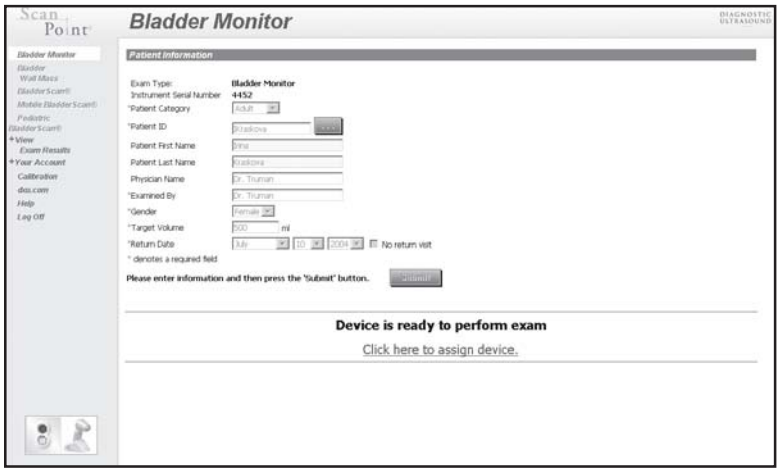
  Note: ** Indicates a required field*

8. When finished, review your information for accuracy and completeness.
9. To submit your information into the database and program the scanning unit, click the Submit button.

   The status box displays the following message: ***"Preparing device for exam ...(percent transmitted)."*** *Transmission will take a few minutes, so please be patient.*



10. When the transmission is completed, confirm that ScanPoint® displays the following screen and message: **"Device is ready to perform exam."**
11. To assign a new scanning unit to another patient, click **"Click here to assign device"**, and then repeat the previous steps.



You have successfully assigned the Bladder Monitor to a patient and can now send the scanning unit home with this patient.

Reassigning the Bladder Monitor to a New Patient

When ScanPoint displays the **Bladder Monitor Patient Information** screen for a scanning unit that has been previously assigned to and used by a patient, the information for the previous patient automatically populates the page. The following procedure describes how to reassign a scanning unit from a previous patient to a new patient.

Important: *Before you send the instrument home with the patient, in order for the instrument to function properly, you must verify that you have updated the patient information so that it is accurate and complete. If you do not review and edit the relevant patient information, the instrument will not perform exams or operate properly for the patient.*

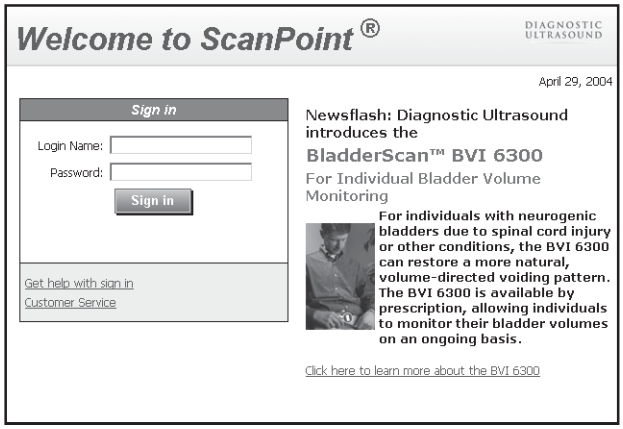
To reassign the Bladder Monitor to a new patient:

1. Place the scanning unit in the communication cradle, which must be connected to your computer. ScanPoint software must also be installed.
2. If you did not install the ScanPoint software from the ScanPoint CD-ROM, ScanPoint prompts you to install it now. To install the ScanPoint software, click **Yes**.

   Note: *If you do not install the ScanPoint software, your scanning unit cannot communicate with ScanPoint, and you will not be able to configure the Bladder Monitor for patient use.*

3. Go to the ScanPoint® website at **https://my.scanpoint.com**, or double-click the **ScanPoint** icon installed on your desktop.

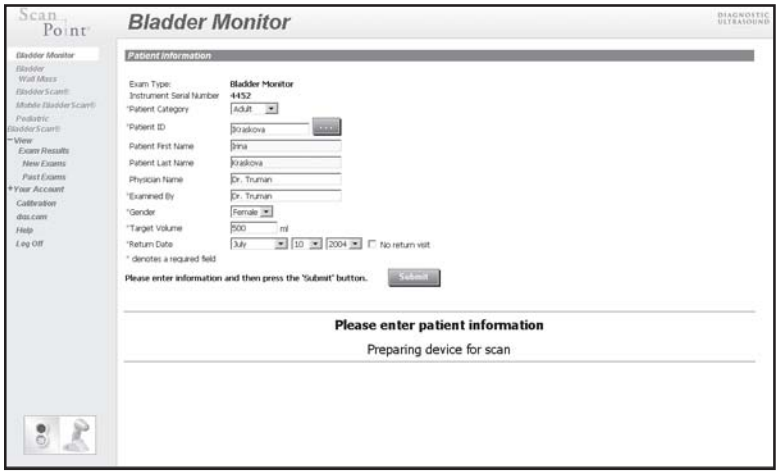
   *ScanPoint displays the **Sign In** screen.*


Welcome to ScanPoint ®
DIAGNOSTIC ULTRASOUND
April 29, 2004
Sign in
Login Name:
Password:
Sign in
Get help with sign in
Customer Service
Newsflash: Diagnostic Ultrasound introduces the
BladderScan™ BVI 6300
For Individual Bladder Volume Monitoring
For individuals with neurogenic bladders due to spinal cord injury or other conditions, the BVI 6300 can restore a more natural, volume-directed voiding pattern. The BVI 6300 is available by prescription, allowing individuals to monitor their bladder volumes on an ongoing basis.
Click here to learn more about the BVI 6300

Field	Action
Login Name	Type the Username that Verathon Corporation assigned to you for logging on to ScanPoint.
Password	Type the secure password that Verathon Corporation assigned to you for logging on to ScanPoint.
Sign In	Click here to log on to ScanPoint.
Get help with sign in	Click here to get help.

4. To log on to ScanPoint, on the **Sign In** screen, type values for the following fields.
   - **Login Name**
     The username that Verathon Corporation assigned to you for logging on to ScanPoint.
   - **Password**
     The password that Verathon Corporation assigned to you for logging on to ScanPoint.
5. Click the **Sign in** button.
   ScanPoint validates your username and password and starts a secure session (identified by the yellow padlock symbol at the lower right-hand corner of the browser window).
6. On the ScanPoint® menu, click **Bladder Monitor**.

*ScanPoint displays the **Bladder Monitor Patient Information** screen, including the information for the previous patient that was assigned to this particular scanning unit.*



7. In the **Patient Profile** section of the screen, enter the relevant information for the new patient to whom you will be assigning this particular scanning unit (replacing the previous patient's data).

   ***Important:** Before you send the instrument home with the patient, in order for the instrument to function properly, you must verify that you have updated the patient information so that it is accurate and complete. If you do not review and edit the relevant patient information, the instrument will not perform exams or operate properly for the patient.*

8. When completed, to submit your information and reassign the scanning unit, click the **Submit** button.

   *The status box displays the following message: "**Preparing device for exam ...(percent transmitted).**" Transmission will take a few minutes, so please be patient.*

9. When the transmission is completed, confirm that ScanPoint displays the following message: **"Device is ready to perform exam."**

   You have successfully reassigned the Bladder Monitor to a new patient.

Editing and Verifying Patient Information for the Bladder Monitor

When ScanPoint displays the **Bladder Monitor Patient Information** screen for a scanning unit that has been previously assigned to and used by a patient, you should review the patient information for accuracy and completeness. If changes and updates need to be made to the information contained on the **Bladder Monitor Patient Information**, you can use ScanPoint to make those updates.

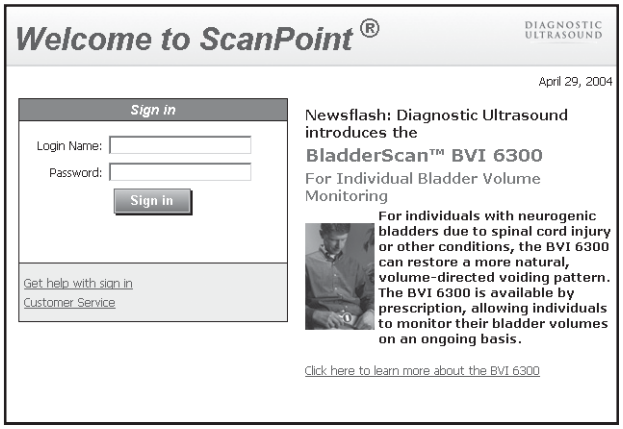
***Important:** Before you send the instrument home with the patient, in order for the instrument to function properly, you must verify that you have updated the patient information so that it is accurate and complete. If you do not review and edit the relevant patient information, the instrument will not perform exams or operate properly for the patient.*

To edit patient information for the Bladder Monitor:

1. Place the scanning unit in the communication cradle, which must be connected to your computer. ScanPoint® software must also be installed.
2. If you did not install the ScanPoint software from the ScanPoint CD-ROM, ScanPoint prompts you to install it now. To install the ScanPoint software, click **Yes**.

   Note: *If you do not install the ScanPoint software, your scanning unit cannot communicate with ScanPoint, and you will not be able to configure the Bladder Monitor for patient use.*
3. Go to the ScanPoint website at **https://my.scanpoint.com**, or double-click the **ScanPoint** icon installed on your desktop.

   *ScanPoint displays the **Sign In** screen.*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Click here to learn more about the BVI 6300

Field	Action
Login Name	Type the Username that Verathon Corporation assigned to you for logging on to ScanPoint.
Password	Type the secure password that Verathon Corporation assigned to you for logging on to ScanPoint.
Sign In	Click here to log on to ScanPoint.
Get help with sign in	Click here to get help.

4. To log on to ScanPoint, on the **Sign In** screen, type values for the following fields.

- **Login Name**

  The username that Verathon Corporation assigned to you for logging on to ScanPoint.
- **Password**

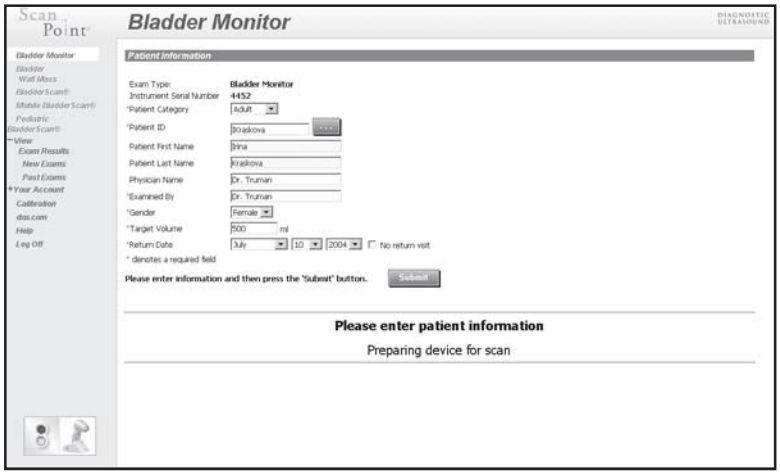
  The password that Verathon Corporation assigned to you for logging on to ScanPoint.

5. Click the **Sign in** button.

   ScanPoint® validates your username and password and starts a secure session (identified by the yellow padlock symbol at the lower right-hand corner of the browser window).

6. On the ScanPoint menu, click BVI 6300.

   *ScanPoint displays the **Bladder Monitor Patient Information** screen, including the information for the previous patient that was assigned this particular scanning unit.*



7. To update or change the patient information, in the **Patient Profile** section of the screen, enter the updated information.

   ***Important:** Before you send the instrument home with the patient, in order for the instrument to function properly, you must verify that you have updated the patient information so that it is accurate and complete. If you do not review and edit the relevant patient information, the instrument will not perform exams or operate properly for the patient.*

8. When completed, to submit your revised information and update the database, click the **Submit** button.

   *The status box displays the following message: **"Preparing device for exam ...(percent transmitted)."** Transmission will take a few minutes, so please be patient.*

9. When the transmission is completed, confirm that ScanPoint displays the following message: **"Device is ready to perform exam."**

   *You have successfully edited existing patient information on the **Bladder Monitor Patient Information page**.*

Measuring Bladder Fullness

After personalizing the Bladder Monitor (BladderScan® BVI 6300) for a patient, healthcare providers should instruct patients on how to measure bladder fullness. This chapter provides instructions for using the Bladder Monitor and training patients to use the instrument.

Turning On the Scanning Unit

To turn on the scanning unit:

1. If the scanning unit is in sleep mode, press and release any button. When the scanning unit chirps, it is ready to scan.
2. Check the battery icon to verify that the battery is sufficiently charged for performing exams. If the battery icon shows no power segments, return the scanning unit to the charging cradle and recharge it before attempting to perform a scan. If the battery icon shows only one power segment, you can perform a few more scans but you will need to recharge your instrument soon.

   Note: *If the scanning unit does not turn on, the battery may be completely discharged. The scanning unit must be charged for six hours before it will be ready for use.*

Applying a Gel Pad

To apply a gel pad:

1. Clean and disinfect the scanhead of the scanning unit by wiping it gently with a germicidal wipe or a soft cloth soaked in isopropyl alcohol.
2. Prepare to apply a Sontac® ultrasound gel pad by peeling back the foil lid of the individual Sontac packaging to expose the gel pad.
3. Patient should lie down or recline as fully as possible and find his or her pubic bone by pressing gently on the lower abdomen.
4. Place the gel pad midline on the abdomen, approximately 1 inch (3 cm) above the pubic bone.

Performing a Measurement

Patients will be able to take both pre- and post-void measurements. Specific instructions should be based on the care plan you provided.

1. **To conduct a pre-void measurement:**
   Press and release the **Top (Gender) button** until the beaker in the upper right hand corner of the LCD screen appears to be full.
2. **To conduct a post-void measurement:**
   Press and release the **Top (Gender) button** until the beaker icon appears empty.
3. When the display is correct, proceed with the scan.
4. Place the scanhead on the gel pad, aimed slightly downward toward the expected location of the bladder. For most people, this means aiming the scanhead toward the coccyx (tailbone).
5. Press and release the **Scan button**, located on the underside of the scanning unit's handgrip.

   Note: *To ensure accurate imaging, make sure the scanning unit is in contact with the gel pad and be sure to hold the scanning unit steady (avoid changing its position, angle, or pressure) until the scan is complete and the instrument beeps; each scan lasts several seconds.*

Important: *The accuracy of your measurement depends on properly aiming the scanning unit. Errors in usage typically result in the underestimation of bladder volume, except when the scanning unit is moved during the scan. In this case, the measurement may overestimate the actual bladder volume. The presence of a catheter in the patient's bladder can also affect the accuracy of scan results by overestimating bladder volume.*

6. After a scan, confirm that the LCD screen displays the following information:
   - **Measured bladder fullness**
     The level of bladder fullness will be represented by the bladder icon in the center of the screen.

Bladder Fullness Level Symbols

Symbol	Meaning	Description
	Empty	0-10% of Target Volume 0 volume segments will be displayed
	Low	11-35% of Target Volume 1 volume segment will be displayed
	Medium	36-60% of Target Volume 2 volume segments will be displayed
	Medium-High	61-85% of Target Volume 3 volume segments will be displayed
	High	86-110% of Target Volume 4 volume segments will be displayed
	Flashing	Greater than 110% of Target Volume
	Aiming arrows	Located on all four sides of the screen, these arrows identify the location of the bladder relative to the scanhead. If the scanning unit was aimed properly, so that the bladder was contained within the image cone, the aiming arrows either will not appear, or will not flash. *Note: The image cone is the cone-shaped range within which ultrasound waves are transmitted by the scanhead during a scan.*

7. If the aiming arrows are flashing, you must re-aim the scanning unit and perform the exam again. Aim the scanning unit in the direction indicated by the arrows and press the **Scan** button again. Repeat this step until the arrows no longer flash.

   Important: *The accuracy of a measurement depends on properly aiming the scanning unit. Errors in usage typically result in the underestimation of bladder volume; however, if the scanning unit was not held still during the scan, the measurement may overestimate the actual bladder fullness.*

Transmitting Exam Data to ScanPoint®

After a Bladder Monitor is personalized and an exam is performed, you can upload the data into the ScanPoint database and use ScanPoint to view and print the final exam results.

To transmit Bladder Monitor exam results:

1. Place the scanning unit in the communication cradle, which must be connected to your computer. You must also have the ScanPoint software installed on your computer. For details, refer to *"Chapter 1. Getting Started."*

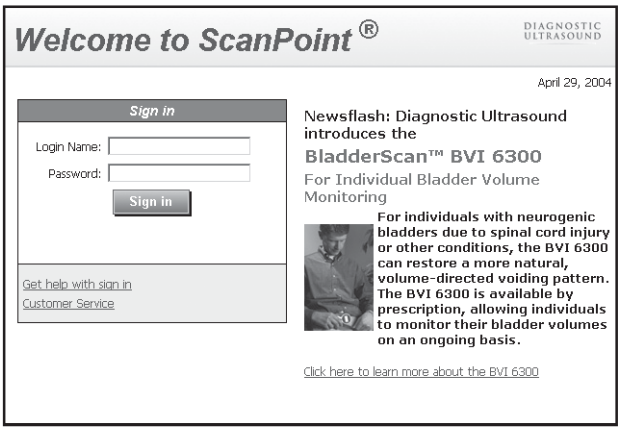
   If you did not install the ScanPoint software form the ScanPoint CD-ROM, ScanPoint prompts you to install it now.

2. If you are prompted to install the ScanPoint software, to install the software, click **Yes**. If your ScanPoint software is already installed, continue to the next step.

   Note: *If you do not install the ScanPoint software, your scanning unit cannot communicate with ScanPoint and you will not be able to transmit exam data to ScanPoint.*

3. Go to the ScanPoint website at **https://my.scanpoint.com**, or double-click the **ScanPoint** icon installed on your desktop.

   ScanPoint displays the ***Sign In*** *screen.*


Welcome to ScanPoint ®
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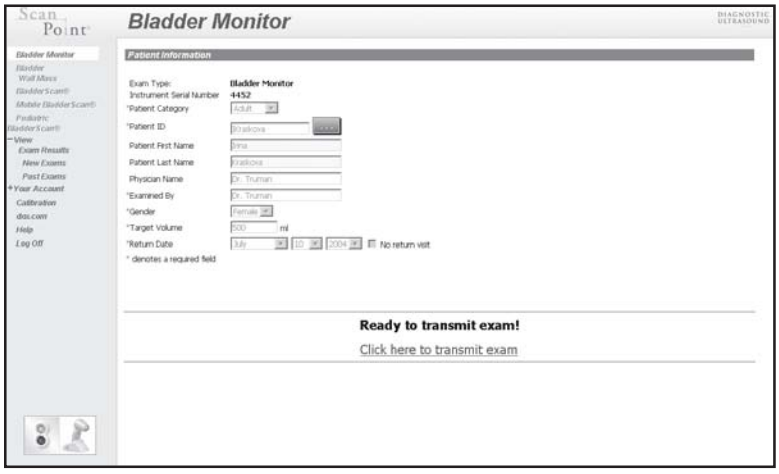
For individuals with neurogenic bladders due to spinal cord injury or other conditions, the BVI 6300 can restore a more natural, volume-directed voiding pattern. The BVI 6300 is available by prescription, allowing individuals to monitor their bladder volumes on an ongoing basis.
Click here to learn more about the BVI 6300

Field	Action
Login Name	Type the Username that Verathon Corporation assigned to you for logging on to ScanPoint.
Password	Type the secure password that Verathon Corporation assigned to you for logging on to ScanPoint.
Sign In	Click here to log on to ScanPoint.
Get help with sign in	Click here to get help.

4. To log on to ScanPoint®, on the **Sign In** screen, type values for the following fields.
   - **Login Name**
     The username that Verathon Corporation assigned to you for logging on to ScanPoint.
   - **Password**
     The password that Verathon Corporation assigned to you for logging on to ScanPoint.
5. Click the **Sign i**n button.

   ScanPoint validates your username and password and starts a secure session (identified by the yellow padlock symbol at the lower right-hand corner of the browser window).
6. On the ScanPoint menu, click **Bladder Monitor**.

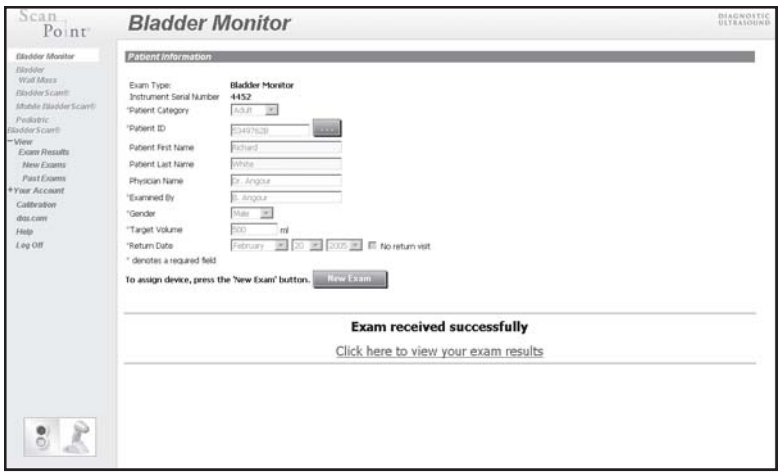
   *ScanPoint displays the **Bladder Monitor** page with the message **"Ready to Transmit Exam!"***



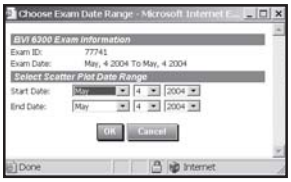
7. In the **Patient Profile** section of the screen, review the information that corresponds to this patient and assigned instrument, including the **Instrument Serial Number** and **Exam Type**.
8. To submit your exam data into the database, click, **Click here to transmit exam** (located at the bottom of the screen).

   *The status box displays the following message: **"Transmitting exam ...(percent transmitted)."** Transmission will take a few minutes, so please be patient.*
9. When the transmission is completed, confirm that ScanPoint® displays the following screen, including the message: **"Exam received successfully."**

10. To view exam results, click the following hyperlink (located at the bottom of the screen): **Click here to view your exam results.**



*ScanPoint displays the **Choose Exam Date Range** dialog box, including **Exam ID** and **Exam Date**.*



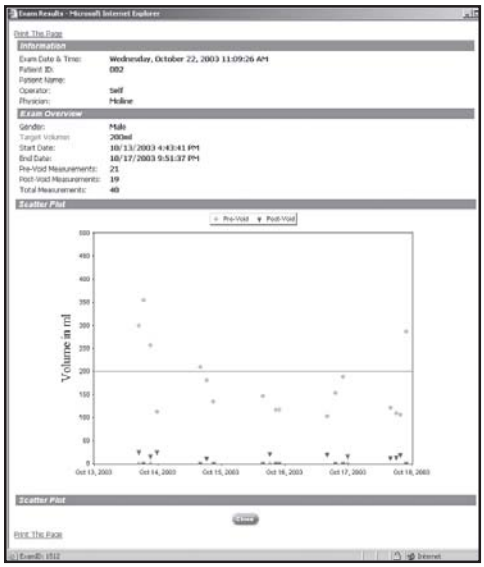
Field	Action
Exam Date	The period between the date the device was assigned to the patient and the date the patient exam data was transmitted to ScanPoint.
Start Date	In the drop-down menus, select a start date range for the exam results that you wish to view.
End Date	In the drop-down menus, select an end date range for the exam results that you wish to view.
OK	Click here to view the exam results based on the date range you specified.
Cancel	Click here to cancel your actions and return to the previous screen.

***Note:** To view an exam, the Start Date and End Date you select must fall within the Exam Date range shown under Bladder Monitor Exam Information.*

11. In the **Select Scatter Plot Date Range** section of the dialog box, use the drop-down menus to select a date range for the exam results that you wish to view.

12. When finished, to view a scatter plot of the exam results from the date range you specified, click **OK**.

    ScanPoint® displays the Exam Results in a scatter plot.



13. To print the exam results scatter plot, click **Print This Page**.

    Your system displays a Windows® Print dialog box.

14. In the **Windows Print** dialog box, select the appropriate print options, and click the **Print** button.

15. To close the window and return to the **Bladder Monitor Patient Information** screen, click the **Close** button.

16. To prepare the scanning unit for patient exams, click, **New Exam** and then verify the patient information as described in the following section titled, "Verifying Bladder Monitor Patient Information at Return Visit."

    Important: *You must verify the patient information before returning the instrument to the patient; if you fail to do so, the instrument will not function properly.*

    Note: *If desired, you also have the option to assign the instrument to a new patient at this time. See the section in this chapter titled, "Reassigning the Bladder Monitor to a New Patient" for details.*

Verifying Bladder Monitor Patient Information at Return Visit

After you transmit a patient's exam data, you must review the **Patient Profile** and update the following information:

- Target volume
- Return date (if applicable)

Important: *Before you send the instrument home with the patient, in order for the instrument to function properly, you must verify that you have updated the patient information so that it is accurate and complete. If you do not review and verify the relevant patient information, the instrument will not perform exams or operate properly for the patient.*

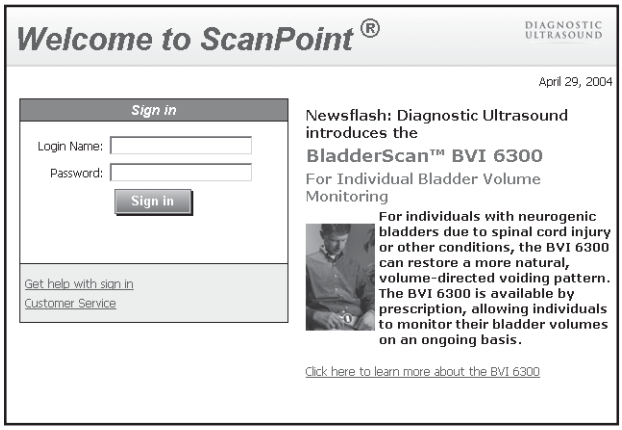
Note: *The following procedure assumes you have already transmitted exam data for the patient to ScanPoint®.*

To review and verify Bladder Monitor patient information:

1. Place the scanning unit in the communication cradle, which must be connected to your computer. ScanPoint software must also be installed.
2. If you did not install the ScanPoint software from the ScanPoint CD-ROM, ScanPoint prompts you to install it now. To install the ScanPoint software, click **Yes**.

   Note: *If you do not install the ScanPoint software, your scanning unit cannot communicate with ScanPoint, and you will not be able to configure the Bladder Monitor for patient use.*
3. Go to the ScanPoint website at **https://my.scanpoint.com**, or double-click the **ScanPoint** icon installed on your desktop.

   ScanPoint displays the ***Sign In*** *screen.*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Click here to learn more about the BVI 6300

Field	Action
Login Name	Type the Username that Verathon Corporation assigned to you for logging on to ScanPoint®.
Password	Type the secure password that Verathon Corporation assigned to you for logging on to ScanPoint.
Sign In	Click here to log on to ScanPoint.
Get help with sign in	Click here to get help.

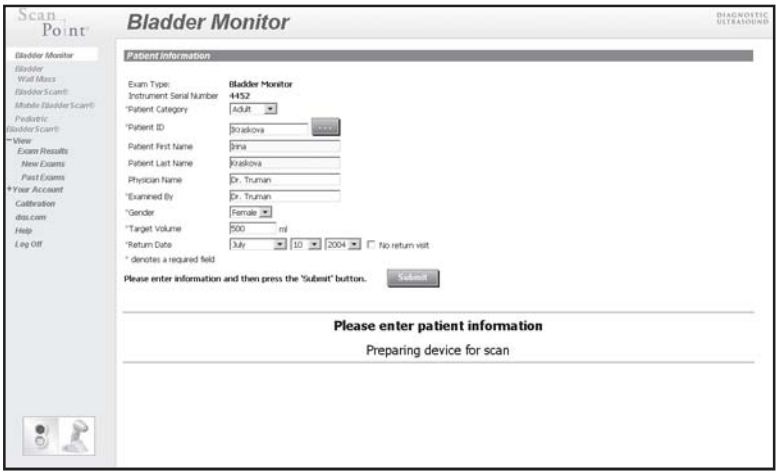
4. To log on to ScanPoint, on the Sign In screen, type values for the following fields.
   - **Login Name**

     The username that Verathon Corporation assigned to you for logging on to ScanPoint.
   - **Password**

     The password that Verathon Corporation assigned to you for logging on to ScanPoint.
5. Click the **Sign in** button.

   ScanPoint validates your username and password and starts a secure session (identified by the yellow padlock symbol at the lower right-hand corner of the browser window).
6. On the ScanPoint menu, click **Bladder Monitor**.

   *ScanPoint displays the **Bladder Monitor Patient Information** screen, including the information for the patient whose information you are reviewing and verifying.*



7. In the **Patient Profile** section of the screen, review the patient information for accuracy and completeness, including:

   - Target Volume
   - Return Date

8. If the information is correct, click the **Submit** button to accept the **Patient Profile**, update the information in the database, and reprogram the instrument. If changes are required (for example, the parameters for the target volume), make the necessary changes, and then click the **Submit** button.

   Important: *Before you send the instrument home with the patient, in order for the instrument to function properly, you must verify and update the patient information so that it is accurate and complete. If you do not verify the patient information, the instrument will not perform exams or operate properly for the patient.*

9. After you click the **Submit** button, confirm that the status box displays the following message: **"Preparing device for exam ...(percent transmitted)."** Transmission will take a few minutes, so please be patient.

10. When the transmission is complete, confirm that ScanPoint® displays the following message: **"Device is ready to perform exam."**

    *You have successfully verified patient information for the **Bladder Monitor**.*

Viewing and Printing Bladder Monitor Exam Results

Once BVI 6300 exam data has been transmitted to ScanPoint, ScanPoint analyzes the data and makes the exam results available to you for viewing and printing. This section describes how to view and print exam results, including:

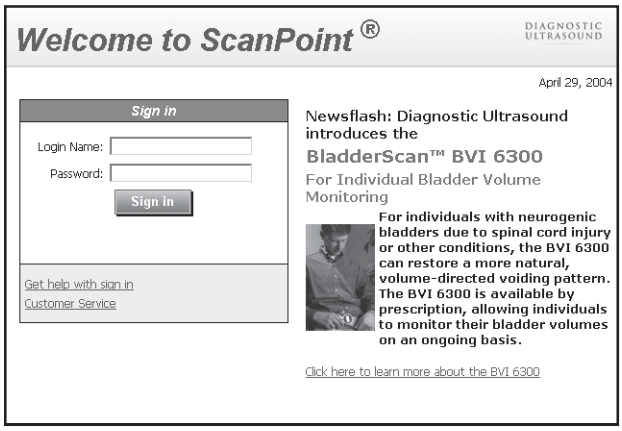
- Viewing and Printing New Exam Results from the BVI 6300
- Viewing and Printing Past Exam Results from the BVI 6300

Viewing and Printing New Bladder Monitor Exam Results

To view and print new exam results from the Bladder Monitor:

1. Go to the ScanPoint website at **https://my.scanpoint.com**, or double-click the **ScanPoint** icon installed on your desktop.

*ScanPoint® displays the **Sign In** screen.*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Click here to learn more about the BVI 6300

Field	Action
Login Name	Type the Username that Verathon Corporation assigned to you for logging on to ScanPoint.
Password	Type the secure password that Verathon Corporation assigned to you for logging on to ScanPoint.
Sign In	Click here to log on to ScanPoint.
Get help with sign in	Click here to get help.

2. To log on to ScanPoint, on the **Sign In** screen, type values for the following fields.

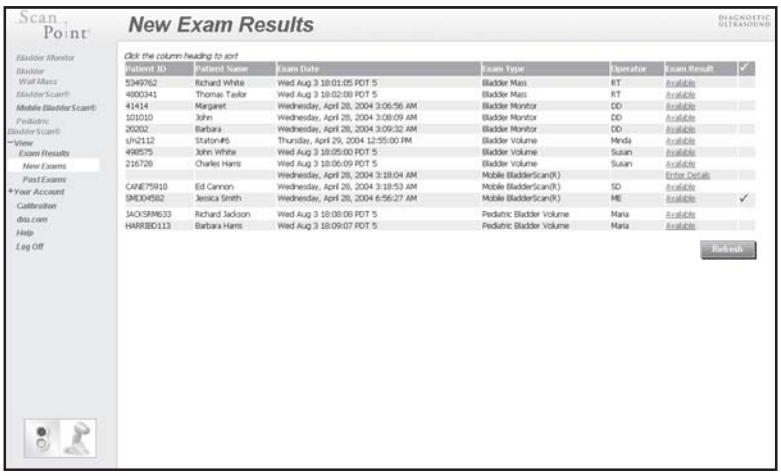
   - **Login Name**
     The username that Verathon Corporation assigned to you for logging on to ScanPoint.
   - **Password**
     The password that Verathon Corporation assigned to you for logging on to ScanPoint.

3. Click the **Sign in** button.

   ScanPoint validates your username and password and starts a secure session (identified by the yellow padlock symbol at the lower right-hand corner of the browser window).

4. On the ScanPoint menu, click **View Exam Results** and then click **New Exams**.

*ScanPoint® displays the **New Exam Results** screen, including an archived list of new exams cross-referenced to a corresponding patient.*



5. To view exam results, in the **Exam Result** column, click the result that corresponds to the relevant patient.

   *ScanPoint displays the **Choose Exam Date Range** dialog box, including **Exam ID** and **Exam Date**.*

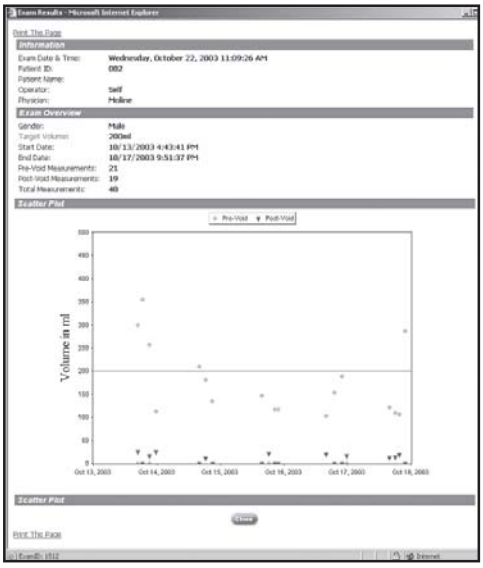
Field	Action
Exam Date	The period between the date the device was assigned to the patient and the date the patient exam data was transmitted to ScanPoint.
Start Date	In the drop-down menus, select a start date range for the exam results that you wish to view.
End Date	In the drop-down menus, select an end date range for the exam results that you wish to view.
OK	Click here to view the exam results based on the date range you specified.
Cancel	Click here to cancel your actions and return to the previous screen.

***Note:** The Start Date and End Date you select must fall within the Exam Date range shown under BVI 6300 Exam Information.*

6. In the **Select Scatter Plot Date Range** section of the dialog box, use the drop-down menus to select a date range for the exam results that you wish to view (exam results will be graphed on a scatter plot).

7. Click **OK** to view a scatter plot for the exam results within the date range you specified.

   ScanPoint® displays the Exam Results in a scatter plot.



8. To print the exam results scatter plot, click **Print This Page**.

   *Your system displays a **Windows® Print** dialog box.*

9. In the **Windows Print** dialog box, select the appropriate print options, and click the **Print** button.

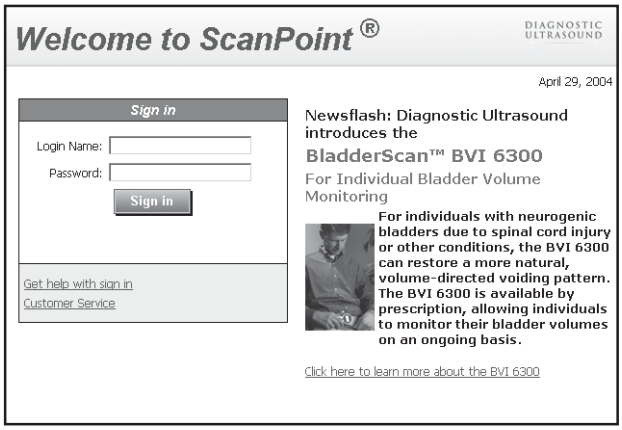
10. To close the window and return to the **New Exam Results** screen, click the **Close** button.

Viewing and Printing Past Bladder Monitor Exam Results

To view and print past exam results from the Bladder Monitor:

1. Go to the ScanPoint® website at **https://my.scanpoint.com**, or double-click the **ScanPoint** icon installed on your desktop.

   *ScanPoint displays the **Sign In** screen.*


Welcome to ScanPoint ®
DIAGNOSTIC ULTRASOUND
April 29, 2004
Sign in
Login Name:
Password:
Sign in
Get help with sign in
Customer Service
Newsflash: Diagnostic Ultrasound introduces the
BladderScan™ BVI 6300
For Individual Bladder Volume Monitoring
For individuals with neurogenic bladders due to spinal cord injury or other conditions, the BVI 6300 can restore a more natural, volume-directed voiding pattern. The BVI 6300 is available by prescription, allowing individuals to monitor their bladder volumes on an ongoing basis.
Click here to learn more about the BVI 6300

Field	Action
Login Name	Type the Username that Verathon Corporation assigned to you for logging on to ScanPoint.
Password	Type the secure password that Verathon Corporation assigned to you for logging on to ScanPoint.
Sign In	Click here to log on to ScanPoint.
Get help with sign in	Click here to get help.

2. To log on to ScanPoint, on the **Sign In** screen, type values for the following fields.
   - **Login Name**

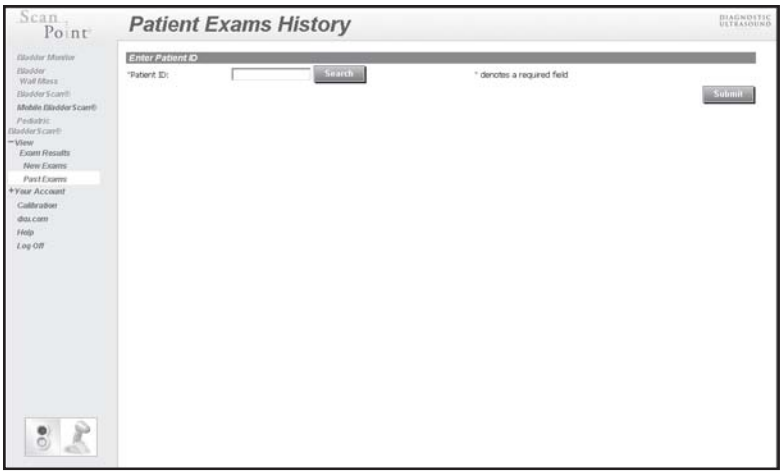
     The username that Verathon Corporation assigned to you for logging on to ScanPoint.
   - **Password**

     The password that Verathon Corporation assigned to you for logging on to ScanPoint.
3. Click the **Sign in** button.

   ScanPoint® validates your username and password and starts a secure session (identified by the yellow padlock symbol at the lower right-hand corner of the browser window).

4. On the ScanPoint menu, click **View Exam Results** and then click **Past Exams**.

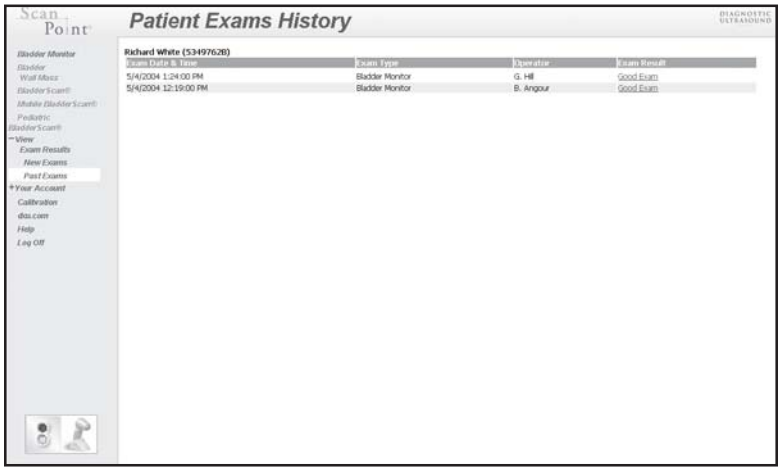
   *ScanPoint displays the **Enter Patient ID** section of the **Patient Exams History** screen.*



Field	Action
Patient ID*	Type the Patient ID that corresponds to the past exams that you wish to view.
. . .	Click here to search the database of patient IDs.
Submit	Click here to search for a customer.

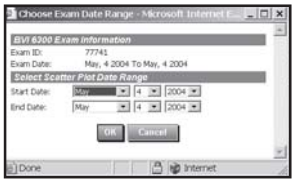
5. In the **Patient ID** text box, type the patient ID for past exams that you wish to view. If you cannot remember the **Patient ID** for an existing patient, click the **Lookup** button, located to the right of the **Patient ID** field.

*ScanPoint® displays the **Patient Exams History** screen, including an archived list of previous exams that are cross-referenced to a corresponding patient.*



6. To view the past exam results, in the **Exam Result** column, click the result that corresponds to the relevant patient and exam date.

   *ScanPoint displays the **Choose Exam Date Range** dialog box, including **Exam ID** and **Exam Date**.*

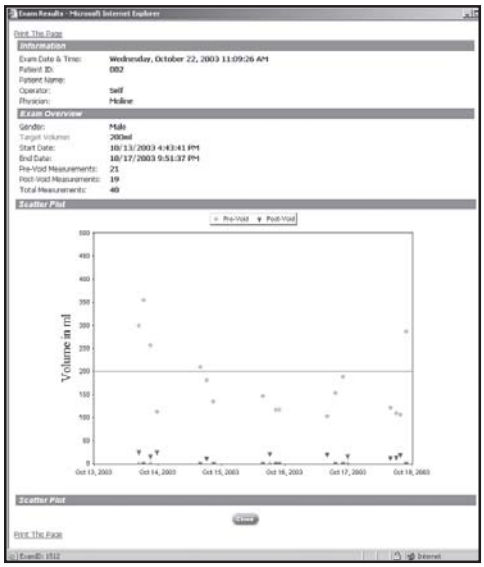


Field	Action
Exam Date	The period between the date the device was assigned to the patient and the date the patient exam data was transmitted to ScanPoint.
Start Date	In the drop-down menus, select a start date range for the exam results that you wish to view.
End Date	In the drop-down menus, select an end date range for the exam results that you wish to view.
OK	Click here to view the exam results based on the date range you specified.
Cancel	Click here to cancel your actions and return to the previous screen.

***Note:** The Start Date and End Date you select must fall within the Exam Date range shown under BVI 6300 Exam Information.*

7. In the **Select Scatter Plot Date Range** section of the dialog box, use the drop-down menus to select a date range for the exam results that you wish to view (exam results will be graphed on a scatter plot).
8. Click **OK** to view a scatter plot for the exam results covering the date range you specified.

   ScanPoint® displays the Exam Results in a scatter plot.



9. To print the exam results scatter plot, click **Print This Page**.

   *Your system displays a **Windows® Print** dialog box.*
10. In the Windows **Print** dialog box, select the appropriate print options, and click the **Print** button.
11. To close the window and return to the **Patient Exams History** screen, click the **Close** button.

Viewing a Bladder Monitor Assignment List

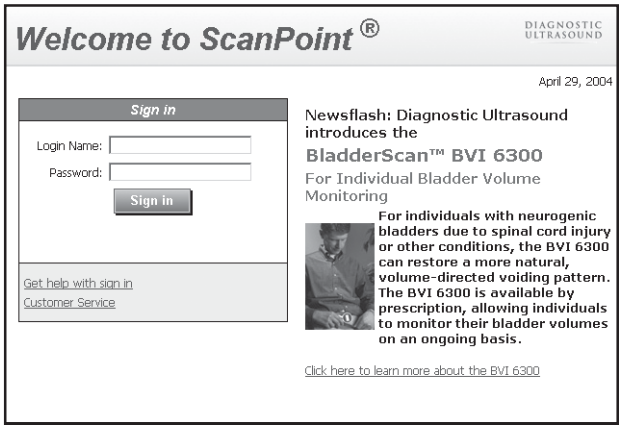
Using ScanPoint®, you can gain access to the ScanPoint database to view the assignment list for a specific scanning unit and view the cross-referenced information associated with the instrument, including patient ID and name, assigned date/time, and return date.

To view a Bladder Monitor assignment list:

1. Place the scanning unit in the communication cradle, which must be connected to your computer. Your computer must also have the ScanPoint software installed.
2. If you did not install the ScanPoint software from the ScanPoint CD-ROM, ScanPoint prompts you to install it now. To install the ScanPoint software, click **Yes**.

   Note: *If you do not install the ScanPoint software, your scanning unit cannot communicate with ScanPoint, and you will not be able to configure the BVI 6300 for patient use.*
3. Go to the ScanPoint website at **https://my.scanpoint.com**, or double-click the **ScanPoint** icon installed on your desktop.

   ScanPoint displays the ***Sign In*** *screen.*


Welcome to ScanPoint ®
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Sign in
Login Name:
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Get help with sign in
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For individuals with neurogenic bladders due to spinal cord injury or other conditions, the BVI 6300 can restore a more natural, volume-directed voiding pattern. The BVI 6300 is available by prescription, allowing individuals to monitor their bladder volumes on an ongoing basis.
Click here to learn more about the BVI 6300

Field	Action
Login Name	Type the Username that Verathon Corporation assigned to you for logging on to ScanPoint.
Password	Type the secure password that Verathon Corporation assigned to you for logging on to ScanPoint.
Sign In	Click here to log on to ScanPoint.
Get help with sign in	Click here to get help.

4. To log on to ScanPoint®, on the **Sign In** screen, type values for the following fields.

   - **Login Name**

     The username that Verathon Corporation assigned to you for logging on to ScanPoint.
   - **Password**

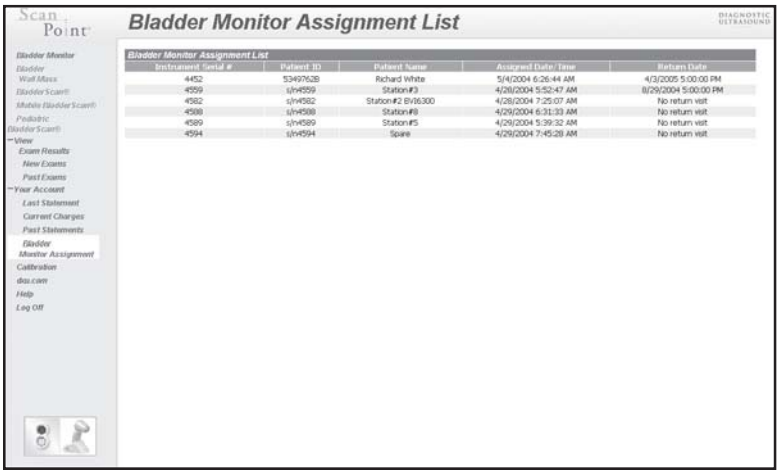
     The password that Verathon Corporation assigned to you for logging on to ScanPoint.

5. Click the **Sign in** button.

   ScanPoint validates your username and password and starts a secure session (identified by the yellow padlock symbol at the lower right-hand corner of the browser window).

6. On the ScanPoint menu, click **Your Account** and then click **Bladder Monitor Assignment**.

   *ScanPoint displays the **Bladder Monitor Assignment List** screen.*



   ***Note:** The annotation "N/A" refers to an instrument that is not currently assigned.*

7. ScanPoint displays the following information on the **Bladder Monitor Assignment List** screen.

   - Instrument Serial Number
   - Patient ID
   - Patient Name
   - Assigned Date/Time
   - Return Date

CHAPTER 5
USING SCANPOINT®

This chapter explains how you can use ScanPoint to enhance and expand the capabilities of your scanning unit.

In This Chapter

- Using ScanPoint
- Understanding User Profiles
- Logging On and Off
- Transmitting Exam Data to ScanPoint (BVI 6100, BVI 6200, BVM 6500)
- Transmitting Mobile BladderScan® Exam Data to ScanPoint (BVI 6400)
- Viewing and Printing New Exam Results
- Viewing and Printing Exam Results for a Specific Patient
- Viewing Your Account Information
- Receiving Email Notifications
- Online Help

Using ScanPoint®

ScanPoint is an online service that integrates with other Verathon Corporation technologies to provide additional features and capabilities. For example, you can use ScanPoint to view, save, and print detailed reports of exam results, to view your account information, and to calibrate your scanning unit.

Note: *For instructions on Installing and Removing the ScanPoint software, see "Chapter 1. Getting Started" in this Urology Suite User's Guide. For information about using ScanPoint in conjunction with the BVI 6300, see "Chapter 4. Assigning the Bladder Monitor (BVI 6300)." For information about using ScanPoint to calibrate your instrument, see "Chapter 6. Inspecting and Maintaining BladderScan."*

About ScanPoint Applications

Without ScanPoint, all BladderScan instruments measure bladder volume (or fullness). For a list of the additional applications available to your instrument model when used in conjunction with ScanPoint, see the following table.

ScanPoint Application	BladderScan BVI 6100	Pediatric BladderScan (BVI 6200)	Bladder Monitor (BladderScan BVI 6300)	Mobile BladderScan (BVI 6400)	Bladder Wall Mass (BladderScan BVM 6500)
View, Save, and Print Exam Results	✓	✓	✓	✓	✓
Calibrate Instrument	✓	✓	✓	✓	✓
Program for Individual User			✓		
Save Data from Multiple Exams				✓	
Record Voice Annotation				✓	
Measure Bladder Wall Mass					✓
View Your Account Information	✓	✓	✓	✓	✓

Understanding User Profiles

The ScanPoint® features available to you depend on the user profile that you requested from Verathon when you purchased your instrument. Your user name and password are associated with this profile.

The following table describes the features available based on your user profile.

Menu Option	Description	Administrative User	Clinical User	Technical User	Purchasing User
Exam Type	Submit patient information, create a new exam record, and transmit the exam data to ScanPoint.	✓	✓		
View Exam Results	View and print the results for new exams and past exams for specific patients.	✓	✓		
Your Account	View account charges for the current month, or billing statements for past months.	✓			✓
Calibration	Calibrate your scanning unit.	✓		✓	
dxu.com	Access Verathon 's corporate website at http://verathon.com/	✓	✓	✓	✓

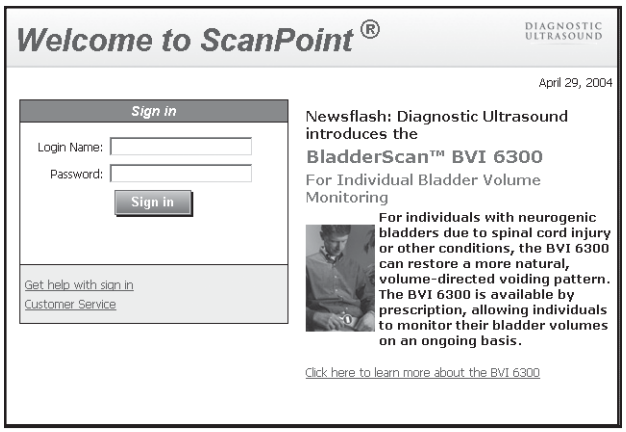
Note: *In accordance with the User Account email that you received from Verathon, your instrument has been set up with the initial user profiles that you selected. If you need to edit or assign new users, please contact Verathon Corporation, or your local representative.*

Logging On and Off

To log on and off:

1. To go to the ScanPoint website, open Internet Explorer and, in the browser.s address bar, type: **https://my.scanpoint.com/**. If you installed the desktop icons from the ScanPoint CD-ROM, you can also double-click the ScanPoint icon on your Windows® desktop.

*Your system displays the **Sign In** screen with the username that you last typed in the **Login Name** field.*


Welcome to ScanPoint ®
DIAGNOSTIC ULTRASOUND
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Sign in
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Sign in
Get help with sign in
Customer Service
Newsflash: Diagnostic Ultrasound introduces the
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Click here to learn more about the BVI 6300

Field	Action
Login Name	Type the Username that Verathon Corporation assigned to you for logging on to ScanPoint®.
Password	Type the secure Password that Verathon Corporation assigned to you for logging on to ScanPoint.
Sign In	Click here to log on to ScanPoint.
Get help with sign in	Click here to get help.

2. To log on to ScanPoint, on the **Sign In** screen, type values for the following fields.

   - **Login Name**
     The username that Verathon Corporation assigned to you for logging onto ScanPoint.
   - **Password**
     The password that Verathon Corporation assigned to you for logging onto ScanPoint.

3. Click the **Sign in** button. ScanPoint validates your username and password and starts a secure session (identified by the yellow padlock symbol at the lower right-hand corner of the browser window).

4. To log off at any time, click **Log Off** (on the ScanPoint menu).

Notes

- If either your Login Name or Password is invalid, ScanPoint® displays the following error message: "Invalid login name or password. Please try again." Attempt to log on again. If you cannot remember your Login Name or Password, or if you need help logging on, click **Get help with sign in**.
- If you are logged on to ScanPoint for a period of time without any activity, ScanPoint logs you off automatically. When you attempt to use ScanPoint after a session has timed out, the Sign In screen will appear, and you will have to log on again.
- If your account has expired, ScanPoint displays the Account Expired screen when you log on. Contact Verathon Corporation to reactivate your account.
- If the credit card for your account expires within 30 days, ScanPoint will prompt you to contact Verathon Corporation and update your credit card information.

Transmitting Exam Data to ScanPoint

(For BladderScan, Pediatric BladderScan, and Bladder Wall Mass exams)

Note: *For instructions on transmitting Mobile BladderScan exams, see the section titled, "Transmitting Mobile BladderScan® Exam Data to ScanPoint," below.*

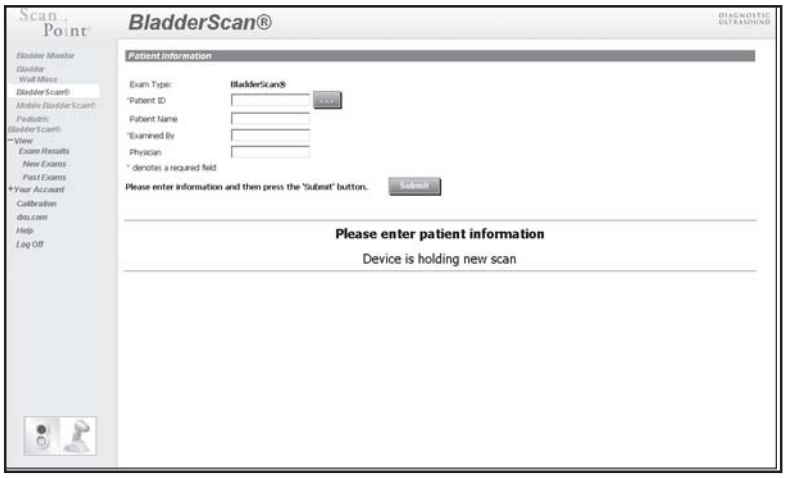
To transmit exam data to ScanPoint:

Note: *For step-by-step instructions that describe how to perform patient examinations, see "Chapter 3. Measuring Bladder Volume and Bladder Wall Mass."*

1. Place your scanning unit in the communication cradle connected to your computer.
2. Go to the ScanPoint website at **https://my.scanpoint.com**, or double click the **ScanPoint** icon installed on your desktop.
3. To log on to ScanPoint, type your **Login Name** and **Password** on the **Sign In** screen, and then click the **Sign In** button
4. On the ScanPoint menu, click the appropriate **Exam** type (i.e., BladderScan, Pediatric BladderScan, etc.).

   If you did not install the ScanPoint driver from the ScanPoint CD-ROM or a newer version of the ActiveX® plug-in is available, a ***Security Warning*** *dialog box prompts you to install it now.*
5. If prompted to install the driver, click **Yes**. If not prompted, or if you have already previously installed the driver, continue to the next step.

*ScanPoint® displays the **Patient Information** screen.*

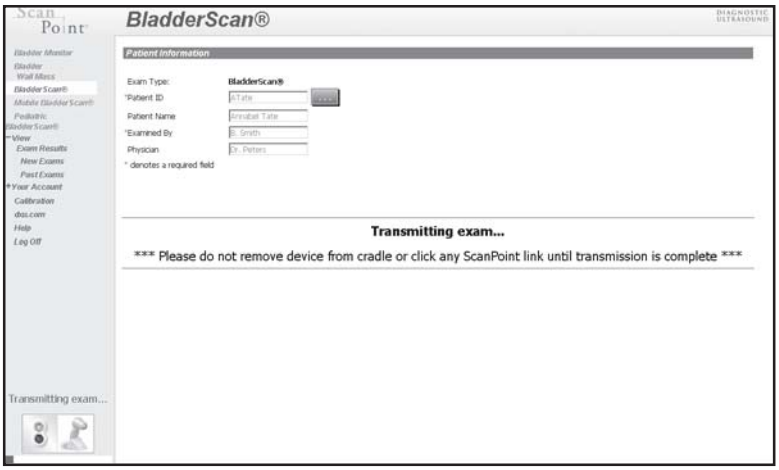


6. Enter the patient information in the fields provided. You must type information in all fields marked with a red asterisk (*).

Field	Description
Exam Type	Displays the type of exam that your instrument is holding.
Patient ID*	Type the identification value that you assigned to the patient in ScanPoint. For a new patient, type a unique Patient ID, and ScanPoint creates a new patient record. *Note: The identification value can be any combination of numbers, letters, or other characters, that you have assigned to the patient in ScanPoint. If you cannot remember the Patient ID for an existing patient, click the Lookup button, located to the right of the Patient ID field. A Patient List displays all the patients in your account. Click the appropriate patient name, and his or her information will appear on the Perform Exam screen.*
...	Click the Lookup button to search for an existing Patient ID.
Patient Name	Type the patient's first and last names. *Note: If you used the Lookup feature to locate the Patient ID, ScanPoint automatically displays the correct patient name associated with the selected Patient ID.*
Examined By*	Type the name of the person who performed the exam.
Physician	Type the name of the patient's physician (the physician who requested the exam).
Submit	Click the Submit button to submit the patient data and transmit the exam to ScanPoint.

7. To transmit the exam, click the **Submit** button.

   The status box displays the following message: ***"Transmitting exam...(percent transmitted)."*** *The data for the patient exam is transmitted from your scanning unit to ScanPoint®, and ScanPoint analyzes the exam data.*



8. When the transmission is completed, confirm that the following message displays: **"Exam received successfully."**

   Note: *If you did not perform the exam before entering the patient information on the* ***Exam Information*** *screen, ScanPoint prompts you to do so now. Perform the exam and return the instrument to the communication cradle. At the bottom of the screen, click,* ***Click here when you have completed the exam****, and then click,* ***Click here and verify patient information****, or click the* ***Submit*** *button.*

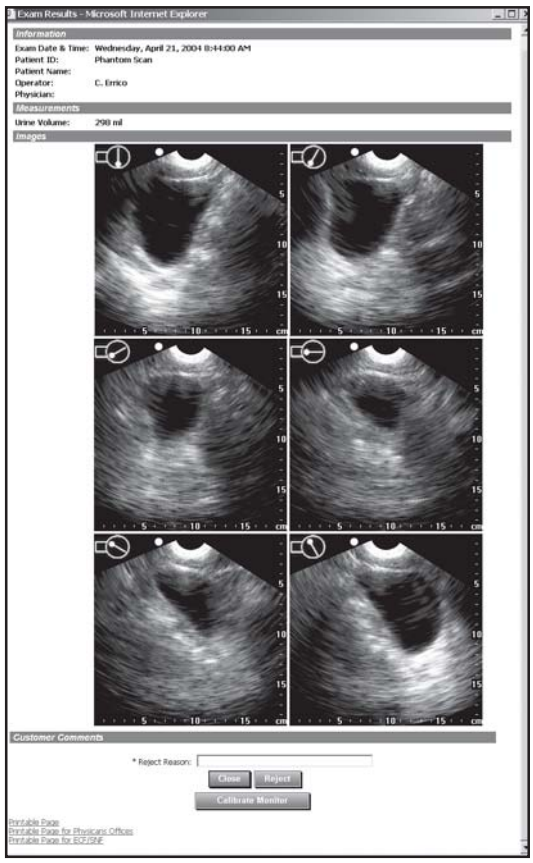
9. If you want to start a new patient exam, click the **New Exam** button and enter the required information.

To view and print the exam results:

10. After the exam data has been successfully transmitted and ScanPoint® has analyzed the data, confirm that ScanPoint displays the following screen.

11. To view your exam results, click the **Click here to view your exam results** link. This link appears within approximately 1-2 minutes after ScanPoint has completed the exam analysis.

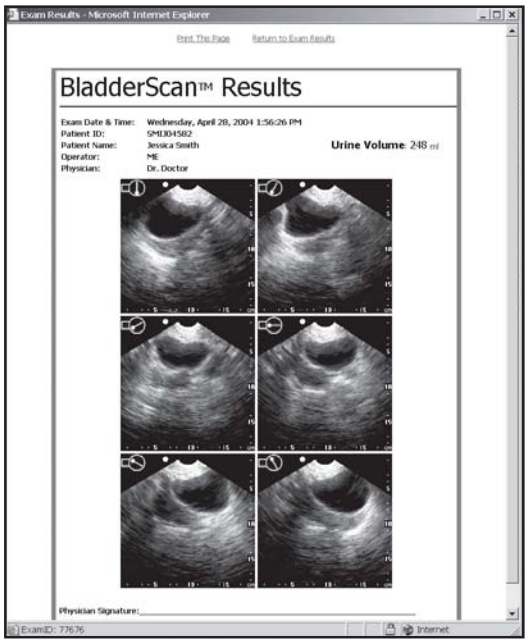
    *ScanPoint displays the **Exam Results** window, including the patient information and ultrasound images from the exam. (**Note:** The images have the orientation shown relative to the BladderScan® — depicted by an icon in the upper left corner of each image.)*



12. To print the exam results, scroll to the bottom of the **Exam Results** window, and then choose one of the available print options.

    - Printable Page
    - Printable Page for Physicians Offices
    - Printable Page for ECF/SNF

After you click one of the print option buttons, ScanPoint® displays the printable ***Results*** *window. (****Note:*** *The orientation of the images relative to the BladderScan® is depicted by an icon in the upper left corner of each image.)*



13. To print, click **Print This Page**.

    Your system displays a ***Windows® Print*** *dialog box.*

14. In the **Windows Print** dialog box, select the appropriate print options, and click the **Print** button.
15. To return to the **Exam Results** window, click **Return to Exam Results**.
16. In the **Exam Results** window, to accept the exam results, click the **Close** button.

    - *To reject the exam results:*
      In the **Reason** field, type a brief description of why you want to reject the results, and then click the **Reject** button. You will no longer be able to view or print exam results after you reject them.

Note: *For more information about using ScanPoint, see the ScanPoint Online Help, which you can access by clicking the* ***Help*** *button on any ScanPoint screen.*

Transmitting Mobile BladderScan® Exam Data to ScanPoint®

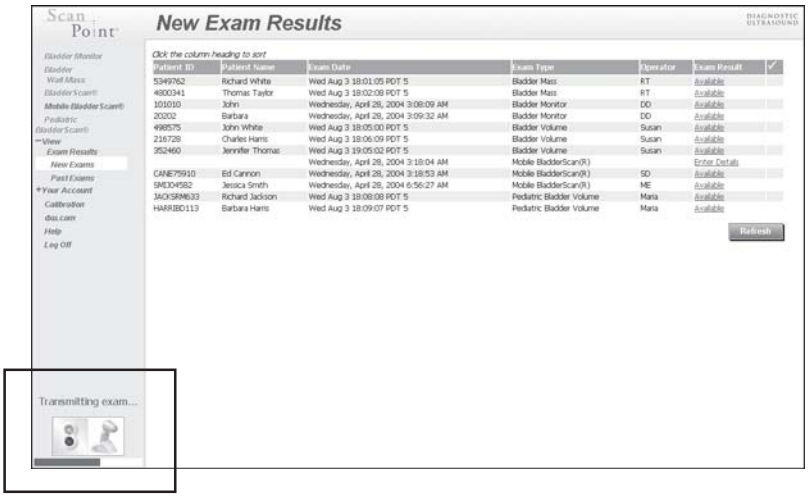
To transmit Mobile BladderScan exam data to ScanPoint:

Note: *For step-by-step instructions that describe how to perform patient examinations, see "Chapter 3. Measuring Bladder Volume and Bladder Wall Mass."*

1. Place your scanning unit in the communication cradle connected to your computer.
2. Go to the ScanPoint website at **https://my.scanpoint.com**, or double click the **ScanPoint** icon installed on your desktop.
3. To log on to ScanPoint, type your **Login Name** and **Password** on the **Sign In** screen, and then click the **Sign In** button

   If you did not install the ScanPoint driver from the ScanPoint CD-ROM or a newer version of the ActiveX® plug-in is available, a ***Security Warning*** *dialog box prompts you to install it now.*
4. If prompted to install the driver, click **Yes**. If not prompted, or if you have already previously installed the driver, continue to the next step.
5. ScanPoint automatically downloads the Mobile BladderScan exams.

   The message "Transmitting Exam" appears above the status box in the lower left corner of ScanPoint.



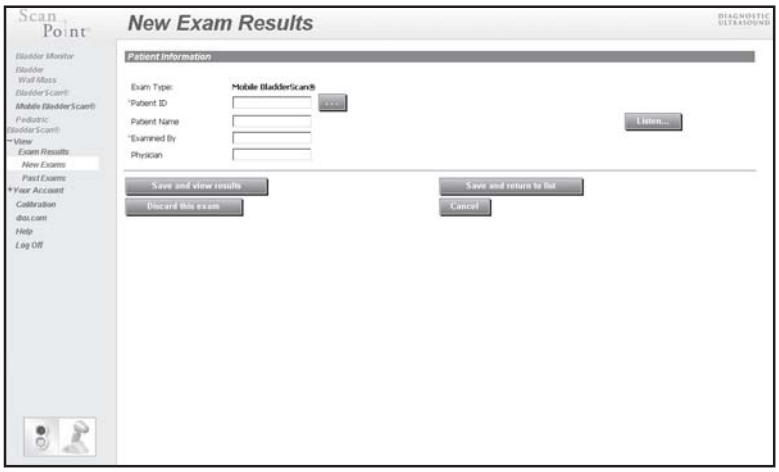
Note: *You may click other ScanPoint options while exams are being transmitted, however you should not remove the Mobile BladderScan from the communication cradle until transmission of the exams is complete and a green light appears in the status box (located in the lower left corner of the ScanPoint screen).*

To view the Mobile BladderScan exam results and enter patient information:

6. After transmission is complete, on the ScanPoint menu, click Exam Results > New Exams to display a list of the new exam results saved on your account.

7. Find the Mobile BladderScan® exam you wish to view and click **Enter Details** in the Exam Result column.

   ScanPoint® displays the Patient Information page.



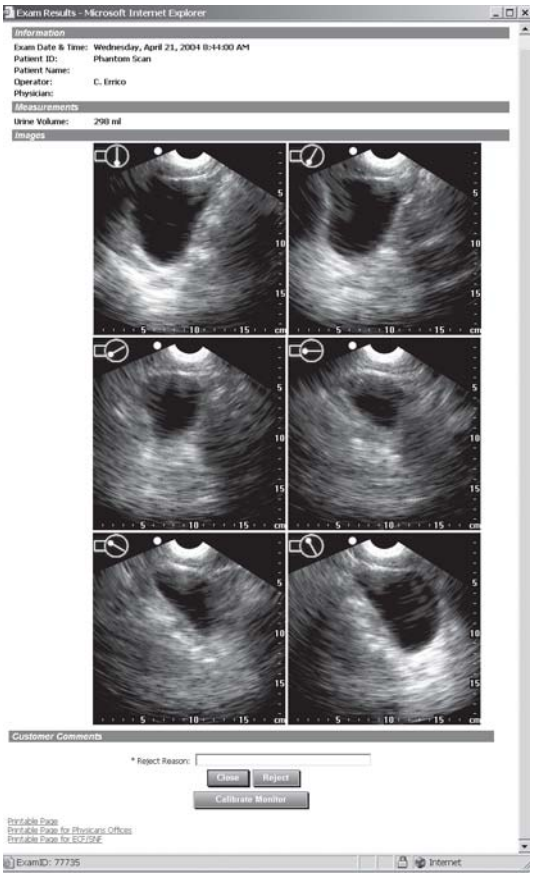
8. Click the Listen button to hear the voice annotation associated with the exam.
9. Enter the patient information in the fields provided. You must type information in all fields marked with a red asterisk (*).

Field	Description
Exam Type	Displays the type of exam that your instrument is holding.
Patient ID*	Type the identification value that you assigned to the patient in ScanPoint. For a new patient, type a unique Patient ID, and ScanPoint creates a new patient record. *Note: The identification value can be any combination of numbers, letters, or other characters, that you have assigned to the patient in ScanPoint. If you cannot remember the Patient ID for an existing patient, click the Lookup button, located to the right of the Patient ID field. A Patient List displays all the patients in your account. Click the appropriate patient name, and his or her information will appear on the Perform Exam screen.*
...	Click the Lookup button to search for an existing Patient ID.
Patient Name	Type the patient's first and last names. *Note: If you used the Lookup feature to locate the Patient ID, ScanPoint automatically displays the correct patient name associated with the selected Patient ID.*
Examined By*	Type the name of the person who performed the exam.
Physician	Type the name of the patient's physician (the physician who requested the exam).
Save and view results	Click the Save and view results button to save the patient information and view the bladder volume measurement and ultrasound images from the exam.

Field	Description
Save and return to list	Click the Save and return to list button to save the patient information and exam data for later viewing. (The exam results will be available on the New Exams page when you wish to review it).
Cancel	Click the Cancel button to return to the New Exams list. (The exam will remain on the New Exams list until you enter the Patient Information and click one of the Save options).
Discard this exam	Click the Discard this exam button to delete the exam.

10. To save and view the exam, click the **Save and View Results** button.

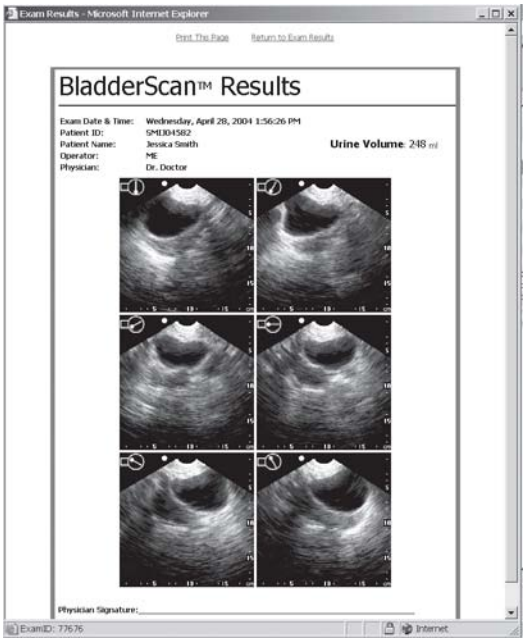
ScanPoint® opens a new window, displaying the results for the selected exam, including multiple views of the ultrasound images. If the exam failed, an error message will describe the failure.
Note: *The orientation of the images relative to the BladderScan® is depicted by an icon in the upper left corner of each image.*



Note: *If you do not want to view the exam results at this time, click the* ***Save and Return to List*** *button. ScanPoint returns to the New Exams list and the exam is saved on the* ***New Exams*** *page for later viewing.*

11. To print the exam results, scroll to the bottom of the **Exam Results** window, and click one of the following print options.
    - **Printable Page**
      Prints the exam and patient identification information and six ultrasound images from the exam.
    - **Printable Page for Physicians Offices**
      Prints the exam and patient identification information, a checklist that allows the physician to identify the patient's medical conditions and history, and six ultrasound images from the exam.
    - **Printable Page for ECF/SNF**
      Prints the exam and patient identification information, a checklist that allows the healthcare facility to identify the patient's medical conditions and history, and six ultrasound images from the exam.

    *ScanPoint® displays the printable **Results** window.*



***Note:** The orientation of the images relative to the BladderScan® is depicted by an icon in the upper left corner of each image.*

12. To print, click **Print This Page**.

    *Your system displays a **Windows® Print** dialog box.*

13. In the **Windows Print** dialog box, select the appropriate print options, and click the **Print** button.
14. To return to the **Exam Results** window, click **Return to Exam Results**.
15. To accept the exam results, click the **Close** button.

- *To reject the exam results:*
  In the **Reason** field, type a brief description of why you want to reject the results, and then clickthe **Reject** button. You will no longer be able to view or print exam results after you reject them.

16. To refresh the list on the **New Exam Results** screen so that you can see which results have not been reviewed, click the **Refresh** button.

***Note:** After you accept the exam results and refresh the New Exam Results screen, the results you just viewed no longer appear in the list of new exams. If you want to view these exam results again, use the Past Exams option on the ScanPoint menu.*

Viewing and Printing New Exam Results

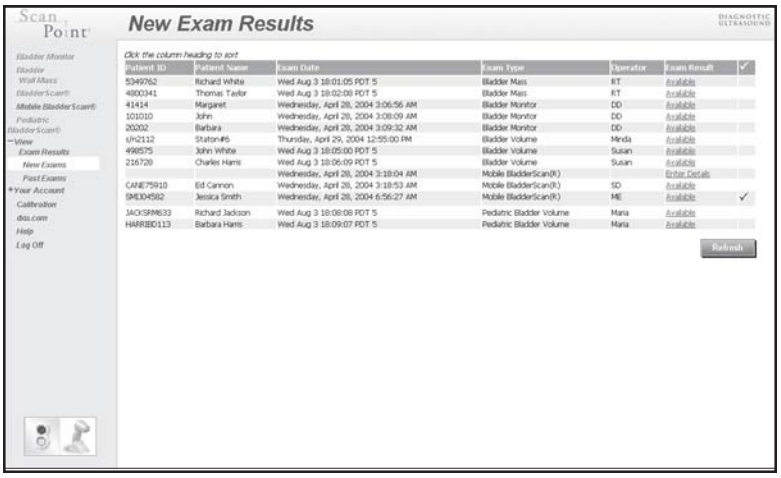
Using ScanPoint®, you can view and print saved exam records at any time, from any computer with an Internet connection. Simply log on to ScanPoint and choose the **View Exam Results** menu option. The results for an exam are typically available within minutes after you transmit the exam data to ScanPoint. When viewing and printing exam results, you do not need to place the scanning unit in the communication cradle. You will be able to view the results only for exams performed at your institution and saved in your institution's ScanPoint account.

Note: *Exams are saved on ScanPoint as New Exams or Past Exams. A New Exam is an exam record that you have transmitted to ScanPoint, but have not yet viewed. Once you view an exam record, it becomes a Past Exam.*

To view and print new (not previously viewed) exam results:

1. Go to the ScanPoint website at **https://my.scanpoint.com/** and log on to ScanPoint.
2. On the ScanPoint menu, click **View Exam Results**, and then click **New Exams**.

   *The **New Exam Results** screen displays a list of new exam results.*

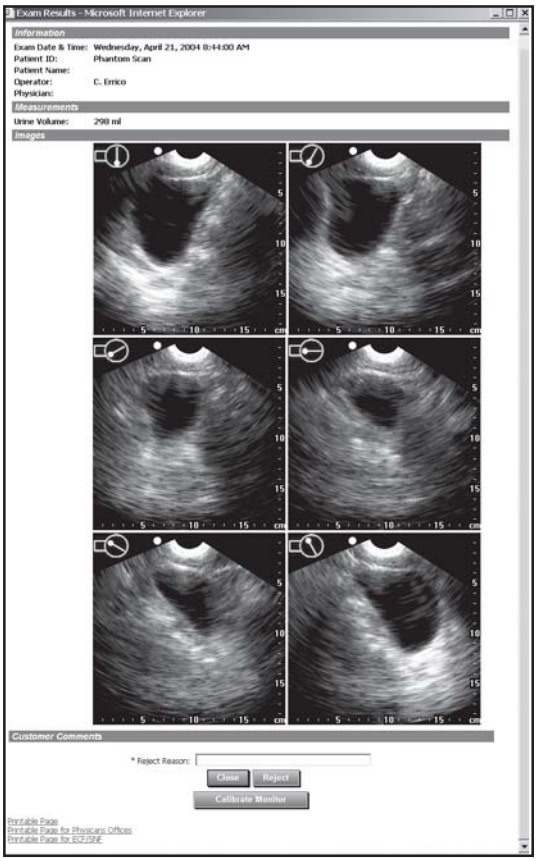


Information	Description
Patient ID	Patient ID numbers include any combination of numbers, letters or other characters that you assigned to the patient in ScanPoint.
Patient Name	The patient's first and last names.
Exam Date & Time	The date (month, day, and year) the exam was performed.
Exam Type	The type of exam that was performed.
Operator	The name of the person who performed the exam.
Exam Result	Possible exam results include: ▪ Available ScanPoint has analyzed the exam data, and the results are ready for your review. ▪ Errors The exam failed, and no results are available for review.

Note: *The information above is included with your exam results, if it was entered at the time of the exam.*

3. To view the results for a specific exam, in the **Exam Result** column, click the result status for that exam.

   ScanPoint® opens a new window, displaying the results for the selected exam, including multiple views of the ultrasound images. If the exam failed, an error message will describe the failure.

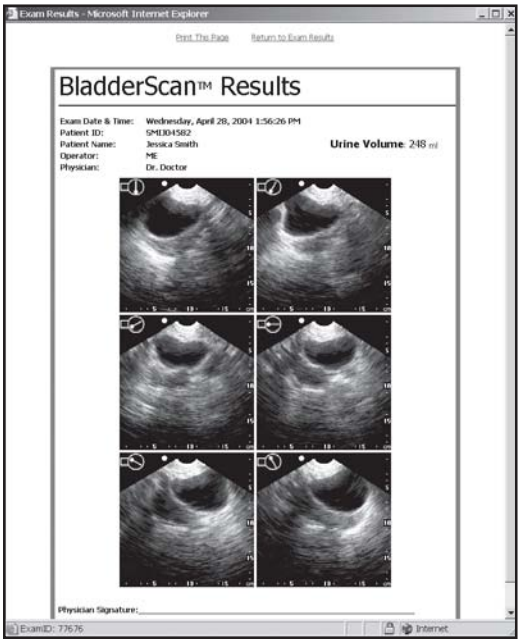


Note: *The orientation of the images relative to the BladderScan® is depicted by an icon in the upper left corner of each image.*

4. To print the exam results, scroll to the bottom of the **Exam Results** window, and click one of the following print options.

   - **Printable Page**
     Prints the exam and patient identification information and six ultrasound images from the exam.
   - **Printable Page for Physicians Offices**
     Prints the exam and patient identification information, a checklist that allows the physician to identify the patient's medical conditions and history, and six ultrasound images from the exam.
   - **Printable Page for ECF/SNF**
     Prints the exam and patient identification information, a checklist that allows the healthcare facility to identify the patient's medical conditions and history, and six ultrasound images from the exam.

*ScanPoint® displays the printable **Results** window.*



***Note:** The orientation of the images relative to the BladderScan® is depicted by an icon in the upper left corner of each image.*

5. To print, click **Print This Page**.

   *Your system displays a **Windows® Print** dialog box.*

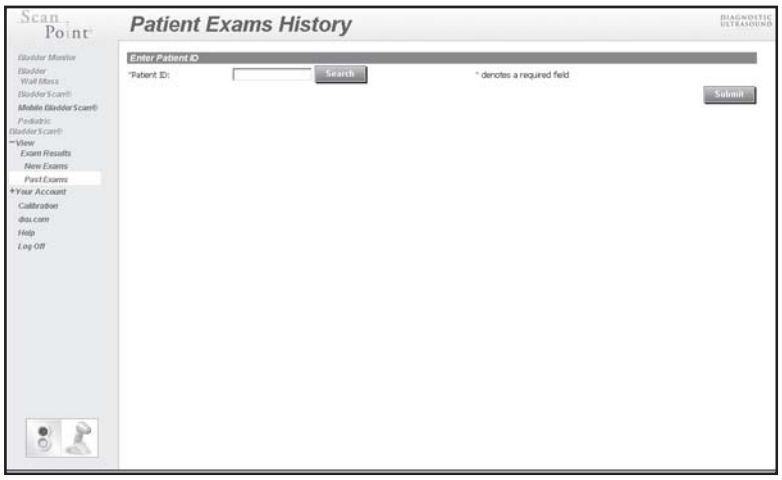
6. In the **Windows Print** dialog box, select the appropriate print options, and click the **Print** button.
7. To return to the **Exam Results** window, click **Return to Exam Results**.
8. To accept the exam results, click the **Close** button.

   - *To reject the exam results:*
     In the **Reason** field, type a brief description of why you want to reject the results, and then clickthe **Reject** button. You will no longer be able to view or print exam results after you reject them.

9. To refresh the list on the **New Exam Results** screen so that you can see which results have not been reviewed, click the **Refresh** button.

***Note:** After you accept the exam results and refresh the New Exam Results screen, the results you just viewed no longer appear in the list of new exams. If you want to view these exam results again, use the Past Exams option on the ScanPoint menu.*

Viewing and Printing the Exam Results for a Specific Patient



To view exam results for a specific patient, simply log on to ScanPoint® and choose the **View Exam Results** menu option. ScanPoint will display a list of all the exam results associated with a selected **Patient ID**.

To view and print exam results for a specific patient:

1. Go to the ScanPoint website at **https://my.scanpoint.com** and log on.
2. On the ScanPoint menu, click **View Exam Results**, and then click **Past Exams**.

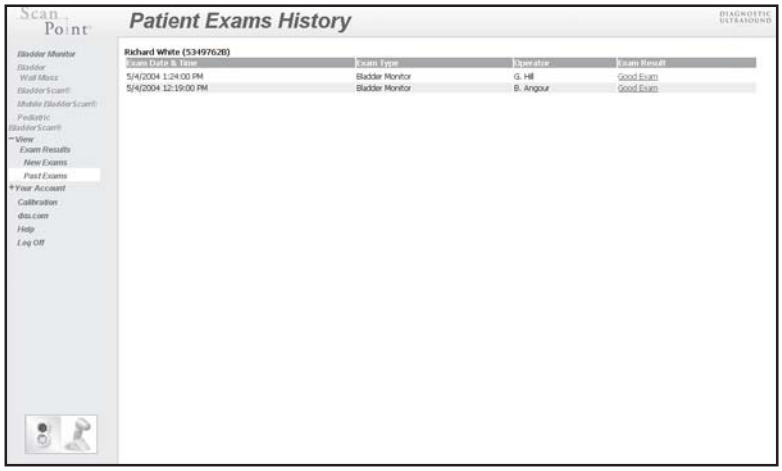
   *ScanPoint displays the **Enter Patient ID** section of the **Patient Exam History** screen*

Information	Description
Patient ID	Type the identification value that you assigned to the patient in ScanPoint.
Search	If you don't remember the Patient ID, click here to look it up.
Submit	Click here to submit the Patient ID and obtain a record of the patient's exam results.

3. On the Patient Exam History screen, enter the **Patient ID** and then click the **Submit** button.

   Note: *If you cannot remember the **Patient ID** for an existing patient, then click the **Search** button, located to the right of the **Patient ID** field. A **Patient List** will appear. Click the **Patient ID** that you want and wait while ScanPoint compiles a list of all past exam results for that patient.*

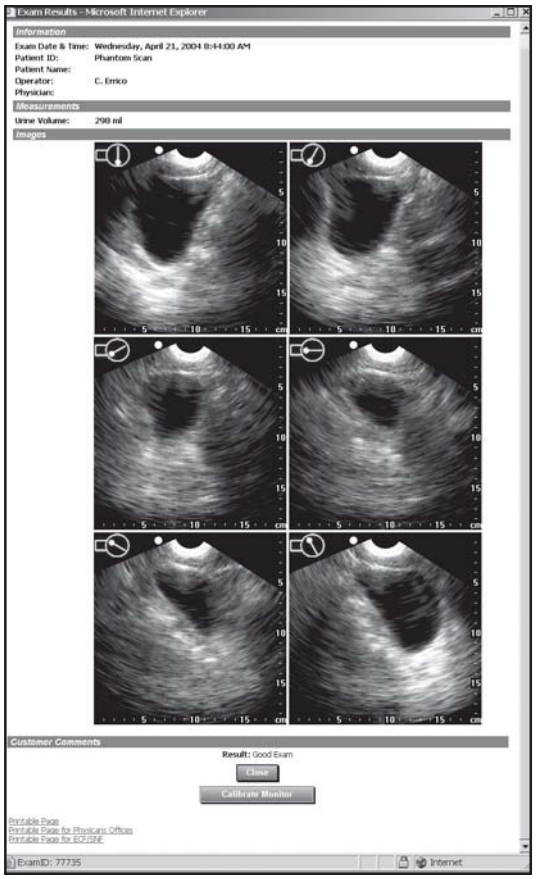
*ScanPoint® displays the **Patient Exam History** screen, including all past exam results for that patient. Exams are sorted by date in descending order, with the most recent exam at the top of the list.*



Information	Description
Exam Date & Time	The date (month, day, and year) the exam was performed.
Patient ID	Type the identification value that you assigned to the patient in ScanPoint.
Exam Type	The type of exam that was performed.
Operator	The name of the person who performed the exam.
Exam Result	Possible exam results include: ▪ Good Exam ScanPoint has successfully analyzed the exam results and the results have been accepted. ▪ Failed exam due to user rejection ScanPoint has successfully analyzed the exam results, but the results have been rejected. ▪ Failed exam due to a ScanPoint server error ScanPoint has experienced a server error, therefore, no results are available for review.

4. To view the results for a specific exam, in the **Exam Result** column, click the result status.

   ScanPoint® opens a new window and displays the results for the selected exam, including multiple views of the ultrasound images. If the exam failed, an error message describes the failure.



   Note: *The orientation of the images relative to the BladderScan® is depicted by an icon in the upper left corner of each image.*

5. To print the exam results, scroll to the bottom of the **Exam Results** window, and click one of the following print options.

   - **Printable Page**

     Prints the exam and patient identification information and six ultrasound images from the exam.

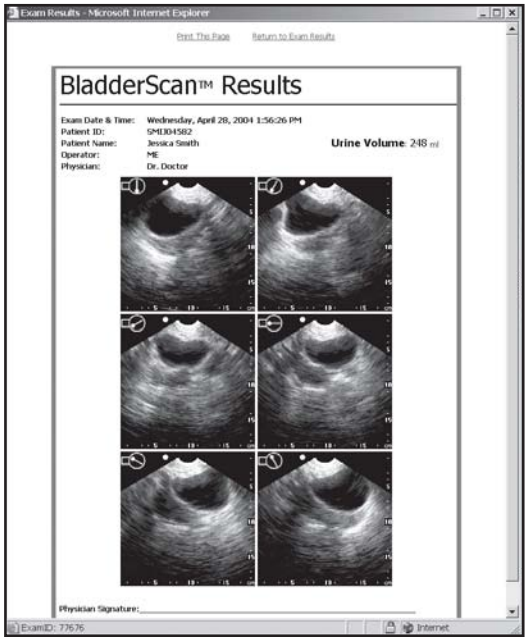
   - **Printable Page for Physicians Offices**

     Prints the exam and patient identification information, a checklist that allows the physician to identify the patient's medical conditions and history, and six ultrasound images from the exam.

   - **Printable Page for ECF/SNF**

     Prints the exam and patient identification information, a checklist that allows the healthcare facility to identify the patient's medical conditions and history, and six ultrasound images from the exam.

*After you click one of the print option buttons, ScanPoint® displays the printable **Results** window.*



***Note:** The orientation of the images relative to the BladderScan® is depicted by an icon in the upper left corner of each image.*

6. To print, click **Print This Page**.

   *Your system displays a **Windows® Print** dialog box.*

7. In the **Windows Print** dialog box, select the appropriate print options, and click the **Print** button.
8. To return to the **Exam Results** window, click **Return to Exam Results**.
9. To close the **Exam Results** window and return to the list of exam results, click the **Close** button.

Viewing Your Account Information

Using ScanPoint®, you can review current account charges or billing statements for previous months. In order to review account charges, you will need to log on with Administrative or Purchasing privileges.

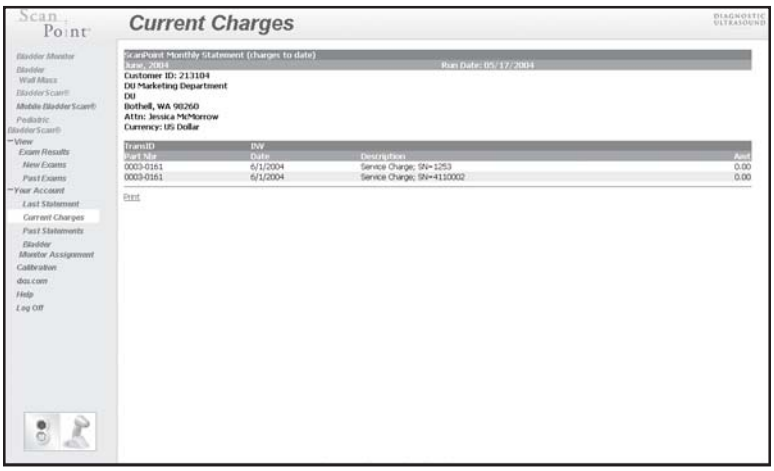
Viewing the Charges for the Current Month

To view charges accrued for the current month, simply log on to ScanPoint and click **Your Account**.

To view the charges for the current month:

1. Go to the ScanPoint website at **https://my.scanpoint.com** and log on.
2. On the ScanPoint menu, click **Your Account**, and then click **Current Charges**.

*ScanPoint displays the **Current Charges** screen, including an itemized list of usage charges and charge details for the current month and identifies how you are paying your account (e.g., credit card, monthly billing or pre-payment). If you have more than one credit card to which the charges are being billed, separate lists will appear for each credit card account number.*



Information	Description
Part Number	The part number for your ScanPoint service plan.
Date	The date of the charges, or the first day of the next month the charges are due.
Description	Your specific ScanPoint service plan, which identifies how Verathon Corporation charges your account and the serial number of the instrument assigned to your service plan
Amount	The total amount of the charges for each month.

***Note:** Current charges do not include applicable sales tax or per use charges. If no charges were made in the current month, the statement "No records" will appear.*

4. To print a copy of your current charges, scroll to the bottom of the statement and click **Print**.

   Your system displays a Windows® Print dialog box.

5. In the **Windows Print** dialog box, select the appropriate print options, and click the **Print** button.

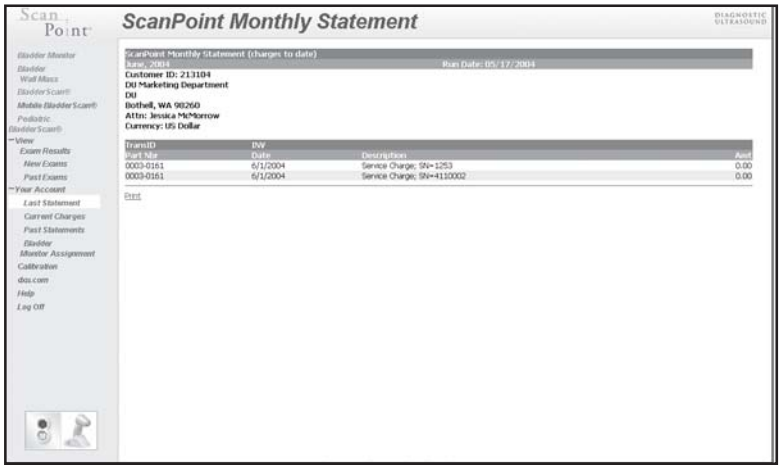
Viewing the Previous Month's Billing Statement

To view the previous month's charges, simply log on to ScanPoint® and click **Your Account**.

To view the billing statement for the previous month:

1. Go to the ScanPoint website at **https://my.scanpoint.com** and log on.
2. On the ScanPoint menu, click **Your Account**, and then click **Last Statement**.

   *ScanPoint displays the **Monthly Statement** screen and an itemized list of usage charges, charge details, and credit card transactions for the previous month. If charges are being billed to more than one credit card, the charges will be listed separately for each card.*



***Note:** If no charges were made that month, the statement, "No records" will appear.*

Credit Card Transactions

For any given month, Verathon Corporation charges the total monthly fees to your credit card on the first day of the following month. **The Credit Card Transactions** section contains information about these charges, including the following:

Information	Description
Date	The date (month, day, and year) that the credit card was charged for the specified month's fees.
Card Type	The type of card, e.g. MasterCard or VISA.
Card Number	The credit card number. For security purposes, only the last four digits of the card number are shown.
DB/CR	Whether it is a debit (DB) or credit (CR) transaction.
Amount	The exact amount being charged to the credit card
Currency	The currency used to calculate the amount, e.g. USD indicates that the amount is specified in U.S. Dollars

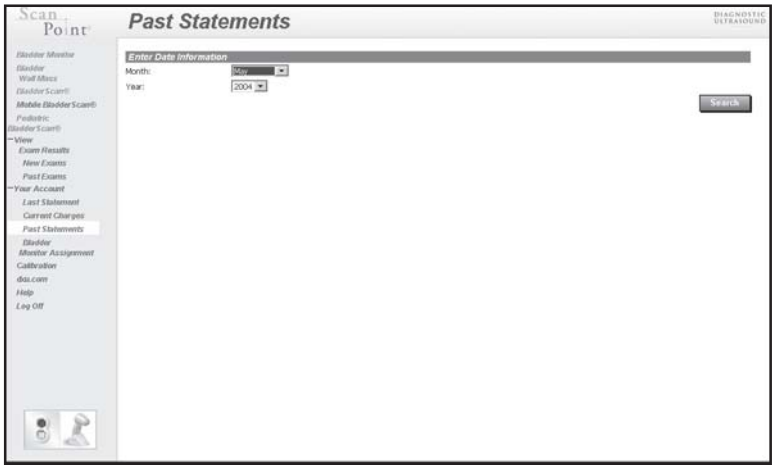
4. To print a copy of the statment, scroll to the bottom of the statement and click **Print**.
   Your system displays a Windows® Print dialog box.
5. In the **Windows Print** dialog box, select the appropriate print options, and click the **Print** button.

Viewing the Billing Statement for Any Past Month

To view billing statements from any past month, simply log on to ScanPoint® and click on **Your Account**.

To view the billing statement for any past month:

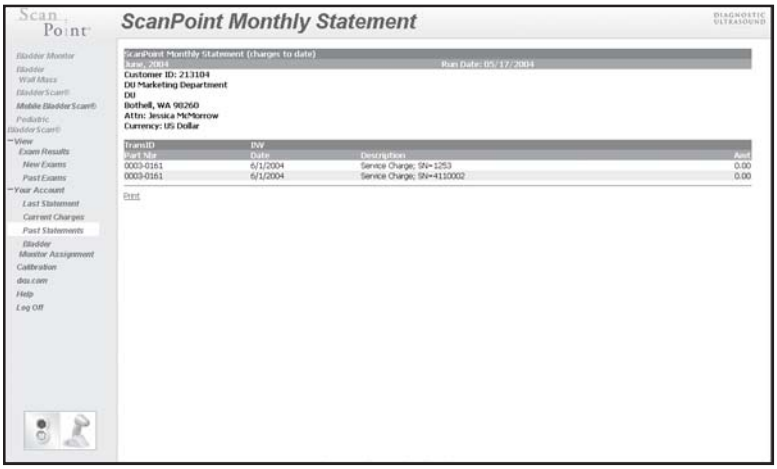
1. Go to the ScanPoint website at **https://my.scanpoint.com** and log on to ScanPoint.
2. On the ScanPoint menu, click **Your Account**, and then click **Past Statements**.
   *ScanPoint displays the **Past Statements** screen.*



Information	Description
Month	Select a month.
Year	Select a year.
Search	Click here to view the billing statement for the selected month and year.

3. From the drop-down menus, select the desired **Month** and **Year** and then click the **Search** button.

   *ScanPoint® displays the **Past Statements** screen, including an itemized list of usage charges, charge details and credit card transactions for the selected month. If charges are being billed to more than one credit card, the charges will be listed separately for each card.*



***Note:** For information about the billing information displayed on the **Past Statements** screen, see the previous section on viewing account charges.*

4. To print a copy of the statment, scroll to the bottom of the statement and click **Print**.

   Your system displays a Windows® Print dialog box.

5. In the **Windows Print** dialog box, select the appropriate print options, and click the **Print** button.

Receiving Email Notifications

This section outlines the automated email messages that are transmitted from ScanPoint®. For a description of the ScanPoint-transmitted email messages that you may receive, refer to the following table:

Description	Message Body
User account edited	*ScanPoint user JohnDoe account information has changed:* • *User Role: [user_role]* • *Name: [user_name]* • *Title: [user title]* • *Language: [user_language]* • *Time Zone: [user_tzone]*
User account added	*Ms. Jane Doe: Your [role_name] login has been created.* • *Login: [user_login]*
User account added.password	*Ms. Jane Doe: Your [role_name] login has been created.* • *Password: [user_password]*
Monthly Statement	*[monthly statement is enclosed/transmitted]*

Online Help

The ScanPoint® online Help system includes detailed information for all ScanPoint menu options, screens, and error messages.

To access the ScanPoint online Help system:

1. Go to the ScanPoint website at **https://my.scanpoint.com/** and log on to ScanPoint. For more information about logging on, see "Logging On and Off," in this chapter.
2. On the ScanPoint menu, click **Help**.

CHAPTER 6
INSPECTING AND MAINTAINING BLADDERSCAN®

This chapter describes how to care for your BladderScan with regular cleaning, weekly inspections, and calibration. You will also find information about replacing your instrument, should the need arise.

In This Chapter

- Cleaning and Disinfecting BladderScan
- Performing Weekly Inspections
- Calibrating the Scanning Unit Using ScanPoint®
- Replacing BladderScan

Cleaning and Disinfecting BladderScan®

To clean and disinfect BladderScan:

1. Use a germicidal wipe or a soft cloth dampened with isopropyl alcohol (or an appropriate hospital cleaning agent) to wipe the scanhead until it is thoroughly cleaned. Cleaning removes any debris, mucous or other substances that may interfere with the performance of the scanning unit.
2. If you use a detergent solution to clean the scanning unit, remove all residual detergent. Dry the instrument with a clean cloth.
3. If the scanning unit needs to be disinfected, dampen a soft cloth in any glutaraldehyde-based hospital disinfectant solution, such as Cidex® or Cidex 7 from Advanced Sterilization Products, or Sporicidin® from Sporicidin International. Wipe the scanning unit with the dampened cloth.

   Warning:

   - Do not immerse the instrument in disinfectant solution.
   - Do not use CidexPlus to disinfect the instrument. CidexPlus is not recommended for use with low-density polyethylene (LDPE) plastic.
   - Do not subject any part of BladderScan to steam sterilization or ethylene oxidesterilization.

     Failure to heed these warnings may cause damage to a BladderScan that is not covered under warranty.
4. To remove all traces of disinfectant solution, wipe the scanning unit with a soft cloth dampened in sterile water or cleaning solution. Verathon Corporation recommends wiping the unit three separate times to remove all residual disinfectant.
5. Thoroughly dry BladderScan with a soft, clean cloth prior to use.

Performing Weekly Inspections

Once a week, you should inspect the scanning unit for physical faults or cracks. Cracks that allow the leakage or ingress of fluid may affect the operation of the instrument.

Caution: *If you see any physical faults or cracks in the scanning unit, discontinue use immediately and contact Verathon customer service or your local BladderScan distributor.*

Calibrating the Scanning Unit Using ScanPoint®

Your ScanPoint warranty allows you to calibrate your scanning unit as often as you like. At minimum, Verathon Corporation requires that you calibrate the instrument every 6-12 months, depending on your Total Reliability Plan℠. Calibrating your scanning unit on a regular basis ensures the maximum accuracy of bladder imaging. The calibration process takes approximately 15 minutes.

Displaying the Days Remaining Until Calibration

The scanning unit itself tracks the number of days remaining until calibration is necessary. When zero days remain until calibration, the scanning unit is disabled, and you will have to calibrate the instrument before using it again. You will know your scanning unit is disabled when “000” and the sun symbol are displayed on the LCD screen.

To display the number of days remaining until calibration for the BVI 6100, BVI 6200, and BVM 6500:

1. Remove the scanning unit from the charging or communication cradle.
2. Press and hold down the **Top (Gender) button**, located on the back of the scanning unit's handgrip, below the LCD screen. When the **Top (Gender) button** is held down for five seconds, the number of days remaining until calibration is displayed on the scanning unit's LCD screen.

   Note: *The actions described in this step do not apply to the BVI 6300 or BVI 6400 scanning unit.*

To display the number of days remaining until calibration for the BVI 6400:

1. Place the scanning unit in the charging or communication cradle.
2. Press and hold down the **Top (Gender) button**, located on the back of the scanning unit's handgrip, below the LCD screen. When the **Top (Gender) button** is held down for three seconds, the number of days remaining until calibration is displayed on the scanning unit's LCD screen.

   Note: *The BVI 6400 must be in the charging or communication cradle, and the cradle must be powered on, for the days remaining until calibration to be displayed.*

Using ScanPoint® for Calibration

In order to calibrate your scanning unit, you must log in with either Administrative or Technical User privileges for ScanPoint.

There are two steps in the calibration procedure:

- Step 1: Preparing the Calibration Targeting System.
- Step 2: Using the prepared calibration targeting system and ScanPoint to calibrate the scanning unit.

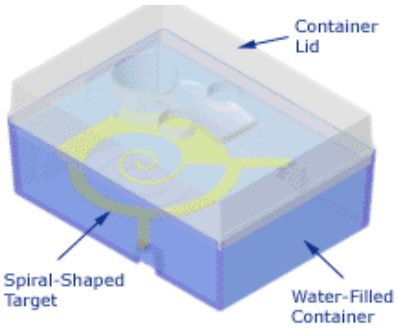
Caution: *The calibration download procedure (and any procedure involving your personal computer) should be performed outside the Patient Vicinity (i.e., more than 6 feet away from the patient). See UL 2601-1 Clause 2 deviation for an exact definition of Patient Vicinity.*

Step 1—Preparing the Calibration Targeting System

1. Place the calibration container on a flat, non-reflective surface and carefully remove the lid. Using clean, room temperature water, pour the water gently into the container—until it reaches the fill-level indicator mark located on the inside of the container. Before continuing, ensure that the water in the tank contains a minimal amount of bubbles.

   If you have filled the container with the correct amount of water, only the black tip of the scanhead will be submerged when you make the calibration measurement.

2. Place the spiral-shaped target in the container, using the notches to position the target correctly.
3. Replace the lid on the calibration container, and place the container on a flat surface.



Step 2—Calibrating the Scanning Unit

1. Place the scanning unit in the communication cradle, which is connected to your computer.
2. Go to ScanPoint® by double-clicking the ScanPoint icon on your Windows® desktop, or by opening Internet Explorer and typing **https://my.scanpoint.com** in the browser's address bar.
3. To log on to ScanPoint, type your **Login Name** and **Password** on the **Sign in** screen, and then click the **Sign in** button.
4. On the ScanPoint menu, click **Calibration**.

   *ScanPoint displays the **Calibration** screen and Instrument Information.*

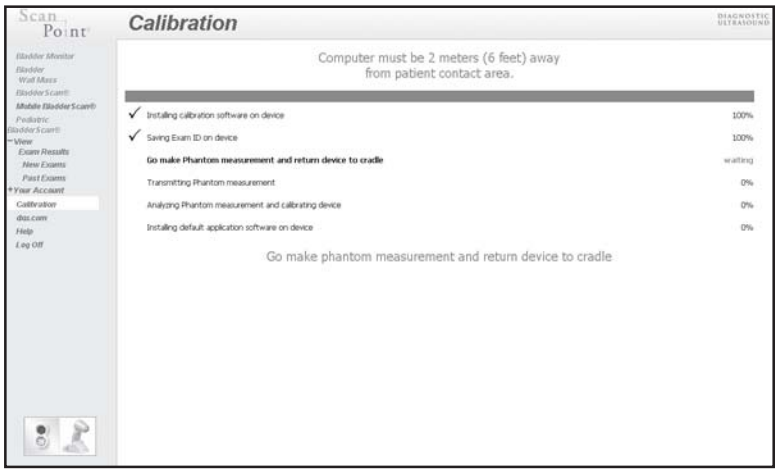
Calibration
Instrument Information
Instrument Serial Number: 4110002
Instrument Model: 570016700
Software Version: 2.028
Remaining Usage Time: 8/27/2005
Calibration Interval: 16 months
Calibration Charge: 0.00 USD
Calibration
Computer must be 2 meters (6 feet) away from patient contact area.
Device ready for calibration - please press the Calibration button to begin.

Information	Description
Instrument Serial Number	Unique serial number assigned to the instrument.
Instrument Model	Model type.
Software Version	Software version currently installed on the device.
Remaining Usage Time	Date and time when the device will require calibration.
Calibration Interval	How often the device requires calibration.
Calibration Charge	Amount that your account is charged for the calibration process, and the currency used to calculate that amount.
Calibration	Click here to begin the calibration process.

5. To verify that ScanPoint has successfully initialized the connection with your scanning unit, locate and review the status box, which contains red and green lights and is located in the lower left corner of the **Calibration** screen. If an error message (e.g., "Could not find device") is displayed below the status box, verify that you positioned the scanning unit correctly in the communication cradle.

6. Click the **Calibration** button.

   *ScanPoint® displays the **Calibrate Instrument** screen, creates a calibration record in the ScanPoint database, and transmits the calibration program to the scanning unit. An "up" arrow appears on the scanning unit's LCD screen, indicating that ScanPoint is transmitting data to the unit. The speed of your Internet connection determines how quickly ScanPoint transmits this data. When completed, the status box reads, **"Go make phantom measurement and return device to cradle...waiting…"** This indicates that you should now begin calibration.*


Calibration
Computer must be 2 meters (6 feet) away from patient contact area.
Installing calibration software on device 100%
Saving Exam ID on device 100%
Go make Phantom measurement and return device to cradle waiting
Transmitting Phantom measurement 0%
Analyzing Phantom measurement and calibrating device 0%
Installing default application software on device 0%
Go make phantom measurement and return device to cradle

7. Remove the scanning unit from the communication cradle and place it in the top of the calibration container. Position the scanhead in the circular cutout so that the black tip of the scanhead is submerged in water.

   ***Important:** The scanhead must make contact with the water; otherwise, the phantom measurement will not be valid.*

8. Press and release the **Top (Gender) button**—located on the top of the scanning unit, below the LCD screen.

9. Wait while the instrument scans the phantom and calibrates.

   The instrument beeps once when the scan is complete and then proceeds to analyze the scan data to ensure that it meets the calibration parameters; the instrument may automatically rescan the phantom, if necessary. When calibration is complete, the instrument chirps and four arrows appear on the LCD screen.

   Important: *Do not remove the instrument from the phantom until four arrows appear on the LCD screen.*

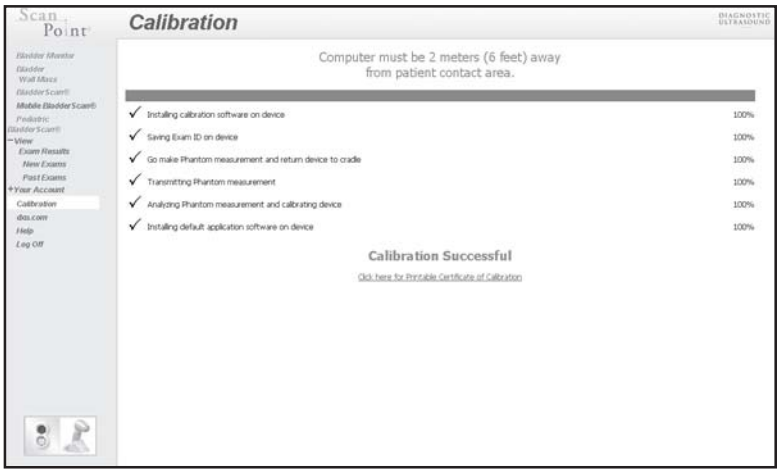
10. Remove the scanning unit from the calibration container, wipe it gently with a clean towel or cloth to remove any water, and place it back in the communication cradle.

    When the scanning unit is placed back in the communication cradle, the scanning unit will beep and automatically begin to transmit the calibration measurement data to ScanPoint®. To indicate that the scanning unit is in the process of transmitting data to ScanPoint, a "down" arrow appears, along with a number indicating the percentage of data remaining to be transmitted.

11. Wait while the scanning unit transmits the calibration results to ScanPoint. ScanPoint then removes the calibration program from your device and prepares the instrument to perform patient exams. Do not remove the scanning unit from the communication cradle until this process is complete.

    Important: *Do not remove the scanning unit from the communication cradle until transmission of the calibration measurement data is complete and a green light appears in the ScanPoint status box.*

    When calibration is complete, the scanning unit beeps and ScanPoint displays the message, ***"Calibration successful"*** *(as shown below).*


Scan Point
Calibration
Computer must be 2 meters (6 feet) away from patient contact area.
Installing calibration software on device 100%
Saving Exam ID on device 100%
Go make Phantom measurement and return device to cradle 100%
Transmitting Phantom measurement 100%
Analyzing Phantom measurement and calibrating device 100%
Installing default application software on device 100%
Calibration Successful
Click here for Printable Certificate of Calibration

12. When you see the **"Calibration Successful"** message, remove the scanning unit from the communication cradle. It is now ready to measure bladder volume.

You will be given the option to print a certificate of calibration. If you wish to print this certificate, click the message, ***Click here for Printable Certificate of Calibration.***

13. Empty the water from the calibration container and dry the container. Always fill the calibration container with clean, room temperature water when calibrating the scanning unit.

    You have successfully calibrated your scanning unit.

Replacing BladderScan®

Verathon Corporation provides full-coverage warranty services for BladderScan through your Total Reliability Plan℠. If you are unable to calibrate or scan, contact Verathon Corporation's Customer Service department and we will send you a replacement, according to the terms of your Total Reliability Plan. General warranty information is contained in "*Chapter 9. Product Specifications"* in this *Urology Suite User's Guide*. For details, see your Total Reliability Plan or talk to your local Verathon representative. For information about how to contact customer service, see *"Chapter 8. Contacting Verathon."*

CHAPTER 7
TROUBLESHOOTING

This chapter provides information to help you identify and resolve minor technical problems that may interfere with the normal operation of BladderScan® and ScanPoint®. It includes a basic troubleshooting guide and descriptions of common problems.

In This Chapter

- Troubleshooting Common Problems
- ScanPoint Error Messages

Troubleshooting

If you are having problems operating BladderScan® or ScanPoint®, review this list of common problems. If you do not find a solution here, contact your authorized BladderScan service center, your local BladderScan distributor or Verathon Corporation. To obtain contact information for Verathon Corporation's Customer Service Center, see *"Chapter 8. Contacting Verathon."*

Common Problems

Problem	Description/ Resolution
The scanning unit does not turn on	This problem is usually caused by a dead or discharged battery. Charge the scanning unit for a minimum of six hours. When your computer is turned on, you can also charge the instrument using the communication cradle. If the scrolling battery icon does not appear after two hours, you will need to activate the scanning unit using the activation tool. Press the activation button with the activation tool. Once activated, replace the scanning unit in its cradle to continue charging. For more information about charging the battery and activating the scanning unit, see *"Chapter 2. Introduction to BladderScan,"* in this *Urology Suite User's Guide*.
The scanning unit is charged but will not scan	If the scanning unit does not measure bladder volume when you press the Scan button, but the battery icon on the scanning unit's LCD screen indicates that the battery has some power remaining, one of the following conditions may apply: ▪ The battery has some power remaining, but not enough to perform bladder imaging. In this case, the battery icon will show only one power segment. Simply place the scanning unit in the charging cradle or communication cradle to recharge the battery. For more information about charging the battery, see *"Chapter 2. Introduction to BladderScan,"* in this *Urology Suite User's Guide*. ▪ You need to calibrate the scanning unit. In this case, the LCD screen displays zero as the number of days remaining until calibration and you must calibrate the scanning unit before you can continue to perform bladder volume measurements. See "Chapter 6. Inspecting and Maintaining BladderScan" for instructions on displaying the days remaining until calibration and calibrating the scanning unit. *Note: This does not apply for the BVI 6300.*
The scanning unit beeps	The scanning unit may beep in the following situations: ▪ You turn on the scanning unit. ▪ The scanning unit goes into *sleep mode* to conserve battery power. ▪ The battery power is low, and the battery requires recharging. In this case, the battery icon will show no power segments. Place the scanning unit in the charging cradle or communication cradle to recharge the battery. ▪ You need to calibrate the scanning unit. In this case, when you press and hold down the Top (Gender) button for five seconds, the LCD screen will display zero as the number of days remaining until calibration. For more information about calibrating the scanning unit, see "*Chapter 6. Inspecting and Maintaining BladderScan,"* in this *Urology Suite User's Guide*. *Note: This does not apply for the BVI 6300.* ▪ The scanning unit performs and completes a bladder volume or calibration measurement. ▪ The scanning unit has begun or finished transmitting data to ScanPoint. ▪ The calibration procedure was successfully completed. ▪ You select or deselect the female option. ▪ You select the pre-void or post-void option.

Problem	Description/ Resolution
Flashing aiming arrows appear on the LCD screen	If flashing aiming arrows appear on the scanning unit's LCD screen after a scan, the bladder was not fully within the *image cone*. You should adjust your aim in the direction indicated by the arrow and rescan the patient. Repeat this process until no flashing arrows appear. When the scanning unit is aimed properly, either a solid arrow or no arrow appears with the bladder volume measurement. For more information about using the aiming arrows, see "*Chapter 3. Measuring Bladder Volume and Bladder Wall Mass,"* in this *Urology Suite User's Guide*.
A solid aiming arrow appears on the LCD screen	A solid arrow indicates an aiming suggestion. The solid aiming arrow appears on the scanning unit's LCD screen when the bladder was not completely centered in the scanning unit's field of vision. In this case, the measurement is good and re-aiming is optional.
A ">" symbol appears before the volume measurement	If a "greater than" symbol (>) appears before the bladder volume measurement, then the bladder is too large to be fully contained within the *image cone*. In such cases, the true volume is greater than the measurement displayed and re-aiming the instrument will not help. This situation occurs almost exclusively in patients with extremely high bladder volumes. At these high volumes, measurements are clinically useful even though they underestimate the actual bladder volume.
An error message appears on the ScanPoint® screen	When you connect to ScanPoint to use its calibration or exam services, an error message may occasionally appear on your computer screen. For information about resolving connectivity problems and other ScanPoint related issues, see ScanPoint Online Help, which you can view by clicking the **Help** button on any ScanPoint screen. You may also contact Verathon's Customer Service support team. See "*Chapter 8. Contacting* Verathon*"* for contact information.
You cannot access the ScanPoint website	If you attempt to access the ScanPoint website and receive a browser error message, your Internet connection may not be working properly. Attempt to view another website to verify that you have Internet access.
You cannot log on to ScanPoint	If you attempt to log on to ScanPoint and receive an error message that states, "Invalid login name or password. Please try again," your username or password may be invalid. Attempt to log on again. If you cannot remember your **Login Name** or **Password**, or you need help logging on, click **Get help with sign in**.
Some menu options are not available	The ScanPoint features that you can use depend on the logon profile that you were assigned by Verathon Corporation. Your user name and password are associated with your profile. You will only have access to menu options that are related to your user profile.

Problem	Description/ Resolution
You cannot find the exam results that you are looking for	When you log on to ScanPoint®, you can view results for any exams that have been transmitted to ScanPoint within your customer account. If you cannot locate the exam that you want to view, you may be attempting to view results for an exam that was not transmitted to ScanPoint within your account. If this is not the case, one of the following conditions may apply: ▪ ScanPoint may not have validated the exam yet. Wait several minutes, and then attempt to view the exam results again. ▪ You may be attempting to view a past exam. If you are looking in the New Exams menu and the exam results have already been viewed, you will find the results in the Past Exams menu.
A "Security Warning" dialog box appears	If you attempt to run ScanPoint on a computer that has an outdated version of the ScanPoint driver or no driver installed, a Security Warning dialog box will eventually prompt you to install it. Click Yes. The ScanPoint driver will be installed from the ScanPoint server.

ScanPoint Error Messages

The following table describes ScanPoint error messages and how to resolve them. The error messages are listed in alphabetical order.

Error Message	Resolution
Account expired.	Contact a customer support representative at Verathon Corporation to reactivate your account.
Comment is too long.	The comment you typed in the rejection Reason field is too long. Type a shorter comment.
Instrument is not responding.	ScanPoint cannot communicate with your scanning unit. Make sure that your scanning unit is positioned properly in the communication cradle. If this error occurred while transmitting data to ScanPoint, click the Submit button to restart the transmission.
Instrument is not working.	Your scanning unit needs to be returned for repair. Please contact a customer support representative at Verathon Corporation for a replacement instrument.
Instrument with given serial and part numbers does not exist. Please contact customer support at 800-331-2313.	You are using a scanning unit that is not registered with ScanPoint. Contact a customer support representative at Verathon Corporation, or your local representative to resolve this problem.
Exam already has exam data uploaded. Please start another exam.	You have already transmitted the exam results associated with the current exam record. You can begin another exam now.

Error Message	Resolution
Exam already has result code set.	You have already accepted or rejected the results for the exam you are viewing. On the New Exam Results screen, click the Refresh button to refresh the list of exam results so that the screen shows only the exams that you have not yet viewed or rejected.
Invalid login name or password. Please try again.	You typed an incorrect Login Name or Password. For help logging in, click Get help with sign in.
Negative values are not allowed.	You cannot type a minus sign (-) as the first character in any ScanPoint® field. Delete the minus sign and submit the information again.
No patient was found with given ID.	You have typed an invalid Patient ID. Type a different Patient ID or click the Lookup button to locate a patient.
Please contact customer support at 800-331-2313.	A ScanPoint problem has occurred that requires assistance from customer support. Please contact a customer support representative at Verathon Corporation, or your local representative.
Your login has expired. Please log in again.	Your ScanPoint session has timed out. You must log in again.
Please restart calibration process.	ScanPoint cannot match the transmitted calibration data to the assigned calibration ID. Please start the calibration process again.
This field may not be empty.	You must enter a value in all fields marked with a red asterisk (*). If you have questions about a specific field, click the Help option on the ScanPoint menu.
This instrument's usage has expired. Please perform calibration before proceeding.	Your scanning unit must be successfully calibrated before you can resume exams.
Unable to initialize duLAP ActiveX® control.	Close all browser windows and attempt to log on again.
Unable to open COM.	Your communication connection with ScanPoint is faulty. Check the cradle's cable connection and your COM port settings.
User's comments may not be empty during exam rejection.	Before you click the Reject button to reject exam results, you must type a rejection reason in the Reason field.
Your credit card will expire soon. Please contact customer service to update your credit card information.	Contact Verathon Corporation, and provide new credit card information for billing. Otherwise, when your current credit card expires, your account will become inactive and you will not be able to use ScanPoint.

CHAPTER 8
CONTACTING Verathon

This chapter contains contact information for Verathon Corporation, and information about additional resources.

In This Chapter

- Contacting Verathon Corporation
- Additional Resources

Contacting Verathon Corporation

The team at Verathon Corporation is committed to modernizing healthcare delivery by putting patients first. Our products support healthcare professionals by providing the highest level of accuracy, utility, and excellence. For additional product and company information, visit the Verathon Corporation website at http://verathon.com/. If you have any questions or comments about Verathon 's products and services, please contact us at:

Corporate Headquarters
21222 30th Drive SE, Suite 120
Bothell, WA 98021
800.331.2313 (US and Canada only)
425.867.1348
Fax: 425.883.2896
E-mail: cservice@dxu.com

Verathon (Europe) B.V.
Lage Dijk-Noord 14
3401 VA IJsselstein The Netherlands
+31.30.68.70.570
Fax: +31.30.68.70.512
Email: service@dxu.nl

Verathon (Japan) K.K.
Executive Tower Azabudai 7F
1-4-3 Azabudai Minato-ku Tokyo, Japan 106-0041
+81.03.3560.3501
Fax: +81.03.3560.3502
Email: service-japan@dxu.com

Verathon (United Kingdom) Ltd.
The Granary Manor Farm Courtyard
Aston Sandford, Aylesbury
Buckinghamshire, HP17 8JB
United Kingdom
+44.1844.299.207
Fax: +44.1844.299.218
Email: customerservice@dxuuk.co.uk

Verathon (France) Sarl
4 Place Arnold
F-67000 Strasbourg
France
+33.03.88.60.14.12
Fax: +33.03.88.60.46.87
Email: service@dxu.nl

Additional Resources

Verathon Corporation provides additional print, video, and online resources to supplement the *Urology Suite User's Guide*. These resources contain more information about using the BladderScan® in conjunction with ScanPoint®.

Additional resources to supplement this *User's Guide* include:

- **ScanPoint Online Help**
  Comprehensive online information, organized by topic to guide you easily through ScanPoint menus and screens.

- **ScanPoint Urology Suite Training CD-ROM**
  This CD-ROM contains the *ScanPoint User's Guide* and quick reference cards and training videos for the instruments in Verathon's Urology Suite (BVI 6100, BVI 6200, BVI 6300, BVI 6400, and BVM 6500).

Some of these items may have been included in the box with your BladderScan. To order additional resources, please contact your local BladderScan distributor or Verathon Corporation.

Additional resources, including training videos, quick reference cards and documentation about BladderScan technology, as well as clinical trials and applications, are available at the Verathon Corporation website, http://verathon.com/.

The Verathon website presents a comprehensive bibliography of clinical papers, with links to summaries of these studies, and describes the benefits and applications of the BladderScan in private practice, acute care, and extended care. Success stories, reimbursement information, and online ordering service are also provided at http://verathon.com/.

CHAPTER 9
PRODUCT SPECIFICATIONS

This chapter describes the technical specifications of BladderScan® and contains information about instrument parts and the product warranty.

In This Chapter

- BladderScan Technical Specifications
- Parts Information
- Warranty
- Symbol Directory

BladderScan® Technical Specifications

The following sections describe the compliance and technical specifications of BladderScan components.

Compliance with Standards

Verathon Corporation certifies that BladderScan and accessories are in compliance with all applicable international and national standards and regulations, including but not limited to the following:

- International Electrotechnical Commission: EN/IEC 60601-1 Amendments 1 and 2 and EN/IEC 60601-1-2 (EMC)
- Medical Device Directive: MDD 93/42/EEC Annex 1
- Canadian Standards Association: C22.2 No. 601.1-M90 (Master Contract No. 177198)
- Underwriters Laboratories, Inc.: UL STD No. 2601-1

Per the MDD, BladderScan is a Class IIa device.

Standard	Classification
	Protection Class II, internally powered equipment
	Type BF, suitable for continuous use

Specifications for the Scanning Unit

The following table identifies the specifications for the scanning unit.

Item	Specification
Power, Weight, Display	
Power	▪ 3.8 v Li Ion rechargeable battery ▪ Power level indicator; 100 consecutive scans on a full charge
Weight	Less than 11 oz. (309 grams)
Display	Liquid crystal
Ultrasound Output Parameters	
Intensity SPTA (Spatial Temporal Average) Power	1.04 mW/cm^2 maximum
Intensity SPPA (Spatial Peak Pulse Average) Power	65.0 W/cm^2 maximum
Mechanical Index (MI)	0.925 maximum
Transducer Dimension	10 mm diameter
Working Frequency Mode	3.7 MHz V-MODE® (multiple, aligned B-mode images)
Scan Angle	120 degrees

Note: *Technical performance assessment (for example, in an acoustic laboratory) may require partial immersion of the scanning unit. Immerse the scanning unit's rounded head no further than the point at which it connects to the body of the scanning unit.*

Accuracy Specification

Given the tremendous variation in healthy and compromised human anatomy, a guaranteed accuracy specification for the instrument used on humans would be difficult. For this reason, the following accuracy specification assumes usage per instructions, scanning a Verathon Corporation tissue equivalent phantom:

Condition	Description
Use	Indoor
Ambient temperature	+10 to +40 degrees Celsius
Atmospheric pressure	70 kPa to 106 kPa
Relative humidity	Maximum is 80% for temperatures up to 31 degrees Celsius, decreasing linearly to 50% relative humidity at 40 degrees Celsius
Water ingress	Rated at IPX1
BladderScan® BVI 6100	
Bladder volume range	0 to 999 ml
Bladder volume accuracy	± 15%, ± 15 ml
BladderScan BVI 6200	
Bladder volume range	0 to 200 ml
Bladder volume accuracy	± 15%, ± 15 ml
BladderScan BVI 6300	
Bladder volume range	0 to 999 ml
Bladder volume accuracy	± 15%, ± 15 ml
BladderScan BVI 6400	
Bladder volume range	0 to 999 ml
Bladder volume accuracy	± 15%, ± 15 ml

BladderScan® BVM 6500	
Bladder volume range	0 to 999 ml
Bladder volume accuracy	± 15%, ± 15 ml
Bladder wall mass range	10 to 150 grams
Bladder wall mass accuracy	± 10 grams

Specifications for the Communication Cradle

The communication cradle plugs into any personal computer through a standard, USB version 1.1 connection. This connection provides both DC power and communications to external devices. The cradle charges the scanning unit using a decoupled transformer design at 200 mA at 4.2 volts (25 kHz).

Condition	Description
Use	Indoor
Ambient temperature	+5 to +40 degrees Celsius
Atmospheric pressure	70 kPa to 106 kPa
Relative humidity	Maximum is 80% for temperatures up to 31 degrees Celsius, decreasing linearly to 50% relative humidity at 40 degrees Celsius
Water ingress	Rated at IPX0 (ordinary equipment without protection against ingress of water)
Computer connection	USB 1.1

Specifications for the Charging Cradle

The charging cradle is tested to EN/EN/IEC 60601-1 requirements and is in compliance with UL and CSA equivalent standards. The charging cradle is not intended for direct patient contact. It is designed to operate within the specifications and environmental conditions identified in the following tables.

Specification	Description
Input voltage	90-264 V AC RMS
Input frequency	47-63 Hz
Input current	2A max
Input connection	Employs direct plug-in AC prongs for wall plug-in units
Insulation	Class II with double insulation to each terminal
Condition	
Use	Indoor
Ambient temperature	+5 to +40 degrees Celsius
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	Maximum is 80% for temperatures up to 31 degrees Celsius decreasing linearly to 50% relative humidity at 40 degrees Celsius
Water ingress	Rated at IPX0 (ordinary equipment without protection against ingress of water)

ScanPoint® Hardware and Software Requirements

To use ScanPoint, your computer must meet the hardware and software requirements identified in the following tables.

Requirement	Minimum	Recommended
Hardware		
Video display	Video card and monitor capable of 800x600 resolution	Video card and monitor capable of 1024x768 resolution
Port	USB 1.1 port	USB 1.1 port
Hard drive	50 MB of available space	50 MB of available space
Memory	128 MB	256 MB
Internet access	56K dial-up modem connection to the Internet. Faster connection strongly recommended.	Digital subscriber line (DSL), cable modem, T1 line or other high-speed connection
Software		
Operating System	Microsoft® Windows® 2000 Professional Service Pack 2	Microsoft Windows 2000 Professional with Service with Pack 3 or Windows XP and latest service pack
Browser	Microsoft Internet Explorer version 6.0	Microsoft Internet Explorer version 6.0 or later

Note: *Make sure that your computer meets the following important requirements:*

- *ScanPoint only works with Internet Explorer version 6.0 or later.*
- *In order for ScanPoint to interface with your scanning instrument, you must also set the Internet Explorer security option,* ***Run ActiveX® controls and Plug-ins****, to* ***Enable****. For more information about setting this security option, see your Microsoft Internet Explorer documentation or the browser's online Help.*

Note: *All procedures involving your personal computer (in which a BladderScan® scanning unit is placed in the communication cradle) should be performed outside the Patient Vicinity (more than 6 feet from the patient). See UL 2601-1 Clause 2 deviation for definition of Patient Vicinity.*

Important: *It is necessary that the computer connected to the USB communication cradle connection be an approved computer certified to minimally EN/IEC 60950/ CSA 950/ UL 1950 or EN/IEC 60601-1/CSA 601.1/UL 2601-1 standards. This configuration ensures that compliance to the EN/IEC 60601-1-1 system standard is maintained. Any person who connects additional equipment to the signal input port or signal output port configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard EN/IEC 60601-1-1. If in doubt, consult your biomedical staff, Verathon's customer service department, or your local representative.*

Specifications for the Calibration Targeting System

The specially designed calibration container is intended to hold a spiral shaped calibration target and 4.2 liters of water. In locating the scanning unit in a known and repeatable location with respect to the spiral target, the calibration container is used with a calibration application to periodically ensure an accurate and proper alignment of the scanner's internal spherical coordinate system and thus, measurement accuracy.

Electromagnetic Effects

There are no restrictions on the use of BladderScan® due to its electromagnetic characteristics. Both the emissions from BladderScan and the susceptibility of this instrument to interference from other sources are within prescribed limits of all applicable standards at the date of manufacture. The emissions test procedure that was used is specified in EN/IEC55011: 1991 for Group 1, Class A equipment (per EN/IEC60601-1-2, 36.201.1.7).

BladderScan is suitable for use in industrial, scientific, and medical (ISM) environments, and in domestic environments under the jurisdiction of a healthcare professional. An indication of adverse electromagnetic effects from BladderScan on another electronic device would be a degradation of performance in the other device when the devices are operated simultaneously. If such interference is suspected, separate the two devices as much as possible, or discontinue simultaneous operation, if practical, and contact Verathon Corporation.

BladderScan will operate normally in the proximity of other potential interference sources, and has demonstrated immunity at a field strength of 3 V/m (per EN/IEC60601-1-2, 36.202.2.1). You do not need to take any other precautions regarding exposure in reasonably foreseeable environmental conditions to magnetic fields, pressure, or variations in pressure, acceleration, or thermal ignition sources.

Parts Information

You can use the part numbers in the following table to order parts and documentation from Verathon .

Part Number	Description
0270-0234	Charging Cradle
0270-0235	Communication Cradle
0620-0225	Calibration Targeting System
0900-0813	ScanPoint® Urology Suite Training CD-ROM
0900-0972	ScanPoint Install CD-ROM
0130-0181	Activation Tool

BladderScan is a completely sealed unit. As such, the BladderScan scanning unit cannot be repaired by the customer or end user. Therefore, Verathon Corporation will not make available any type of circuit diagrams, component parts lists, descriptions, or other information that would be required for repairing BladderScan. If you have any questions, please contact your Technical Service Representative.

Warranty

Verathon Corporation warrants BladderScan® against defects in material and workmanship as long as it is covered by the ScanPoint® Total Reliability Plan℠. This warranty does not cover equipment sold as used.

Damage or loss insurance is available as part of the Total Reliability Plan. Pursuant to this warranty, a service center authorized by Verathon Corporation will repair or replace products that prove to be defective during the warranty period.

This warranty does not apply if the product has been damaged by misuse or as the result of service or modification by anyone other than a service center authorized by Verathon Corporation.

The instrument must be used in accordance with the instructions contained in this *Urology Suite User's Guide*. Consumable items should be used in conformance with Verathon Corporation product specifications. Consumable items are not covered under this warranty.

For further details, consult your ScanPoint Total Reliability Plan. Warranty conditions may differ in some countries outside the United States. Contact your local distributor for warranty terms.

Disclaimer of Additional Warranties

There are no understandings, agreements, representations of warranties expressed or implied (including warranties of merchantability or fitness for a particular purpose) other than those set forth in the preceding **Warranty** section. The contents of this *User's Guide* do not constitute a warranty.

Some states disallow certain limitations on applied warranties. The purchaser, user, and patient should consult state law if there is a question regarding this disclaimer. The information, descriptions, recommendations, and safety notations in this handbook are based upon Verathon Corporation's experience and judgment, as of May 2004, with respect to BladderScan. This is a new product involving a relatively new area of medical technology. The contents of this handbook should not be considered to be all-inclusive, or to cover all contingencies.

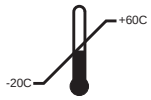
The physician who directs the use of BladderScan at your institution is responsible for keeping current with developments in the literature on bladder volume. Please direct any questions or problems concerning bladder volume, the use of this instrument, or the interpretation of data, to the responsible physician.

Disposal of Device

At the end of equipment useful service life the user should return the device to The Verathon Corporation.

Symbol Directory

The following table identifies the industry symbols used to classify BladderScan®.

Symbol	Description
	Class II equipment
	Type BF applied part (used to identify a type BF applied part with EN/IEC-60601-1)
	CE marked in accordance to the MDD
	CSA symbol
	Attention, consult accompanying documents
	Ambient temperature, storage conditions
	Atmospheric pressure, storage conditions
	Relative humidity, storage conditions

APPENDIX A
SCANPOINT® LEGAL INFORMATION

This appendix contains legal documents that apply to the ScanPoint service. For the latest versions of these legal documents, see the Verathon Corporation website at: **http://verathon.com/**.

In This Appendix:

- The Verathon Corporation HIPAA Business Associate Agreement
- Health Insurance Portability and Accountability Act (HIPAA) Compliance Statement

The Verathon HIPAA Business Associate Agreement

This BUSINESS ASSOCIATE AGREEMENT (this "~~Agreement~~") is made and entered into as of the Effective Date by and between DU and Client.

RECITALS

Contemporaneously with this Business Associate Agreement, DU and Client have entered into a ScanPoint Total Reliability Plan Agreement of even date herewith (the "~~Service Agreement~~") as a consequence of which the parties expect and intend that DU will be a business associate of Client under the Social Security Act and applicable regulations relating to Protected Health Information (collectively, the "~~HIPAA Privacy Rules~~"). Consequently, this Agreement applies when DU acquires any information in the course of its duties under the Service Agreement that is Protected Health Information (PHI) received from, or created or received by DU on behalf of Client under the HIPAA Privacy Rules.

In consideration of the promises and of the mutual agreements and covenants hereinafter set forth, and other valuable consideration, receipt and sufficiency of which each of the parties hereby acknowledges, the parties agree as follows:

1. Definitions

Capitalized terms used, but not defined, in this Agreement shall have the same meaning as in 45 CFR §§ 160.103 and 164.501. Capitalized terms used herein but not defined herein or in 45 CFR §§ 160.103 and 164.501 shall have the meanings given them in the Service Agreement. Unless otherwise stated, a reference to a "Section" is to a section of this Agreement. All definitions are equally applicable to plural and singular defined terms. A reference in this Agreement to a section in the HIPAA Privacy Rules means the section as in effect or as amended.

2. Permitted Use or Disclosure of PHI by DU

DU may not use or disclose PHI except as follows:

2.1 Except as otherwise limited in this Agreement, DU may use or disclose PHI to perform functions, activities, or services for, or on behalf of, Client as specified in the Service Agreement, provided that such use or disclosure would not violate the HIPAA Privacy Rules if made by Client.

2.2 DU may use PHI as necessary for the proper management and administration of its business or to carry out its legal responsibilities.

2.3 DU may disclose PHI if disclosure is required by law.

2.4 DU may disclose PHI if DU obtains reasonable assurances that the PHI will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed; and any person to whom the PHI is disclosed notifies DU of any instances of which it is aware in which the confidentiality of the information has been breached.

2.5 DU may provide Data Aggregation services to Client as permitted by 42 CFR 164.504(e)(2)(i)(B).

3. Obligations of DU Relating to Client's PHI

3.1 DU will use appropriate safeguards to prevent use or disclosure of PHI other than as permitted by this Agreement.

3.2 DU will report to Client any impermissible use or disclosure of PHI of which it becomes aware.

3.3 DU will require its agents or subcontractors, if any, to whom it provides PHI to agree to the same conditions that are applicable to DU's use or disclosure of PHI under this Agreement.

3.4 DU will do the following in accordance with the HIPAA Privacy Rules:

3.4.1 Make PHI about an individual available to that individual on request.

3.4.2 Make PHI available for amendment and incorporate any amendments, on request.

3.4.3 Document such disclosures of PHI and information related to such disclosures as would be required for Client to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528.

3.4.4 Provide to Client, in the time and manner reasonably requested by Client and subject to any applicable extra charge, information collected in accordance with Section 3.4.3 of

this Agreement, to permit Client to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528.

3.4.5 Make its internal practices, books and records relating to the use and disclosure of PHI available to Client or, at Client's request, to the U.S. Department of Health and Human Services for purposes of determining compliance.

3.4.6 At the termination of the Service Agreement, DU will (a) if feasible, return to Client or destroy all PHI received from, or created or received by DU on behalf of, Client that DU still maintains in any form and retain no copies; or (b) if return or destruction is not feasible, extend the protections of this Business Associate Agreement to the PHI and limit further uses and disclosures to those purposes that make return or destruction infeasible.

4. Obligations of Client Relating to DU's Use of Client's PHI

4.1 Client shall provide DU with a copy of the notice of privacy practices that Client produces in accordance with 45 CFR § 164.520, as well as any changes to such notice.

4.2 Client shall provide DU with any changes in, or revocation of, permission by any Individual to use or disclose PHI, if such changes affect DU's permitted or required uses and disclosures.

4.3 Client shall notify DU of any restriction to the use or disclosure of PHI that Client has agreed to in accordance with 45 CFR § 164.522.

4.4 Client shall not request DU to use or disclose PHI in any manner that would not be permissible under the HIPAA Privacy Rules if done by Client, except as provided by Sections 2.2 and 2.5 of this Agreement.

5. Term and Termination

5.1 The Term of this Agreement shall begin on the Effective Date, and shall terminate when all of the PHI provided by Client to DU, or created or received by DU on behalf of Client, is destroyed or returned to Client; or, if it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provisions in this Section.

5.2 Upon Client's knowledge of a material breach by DU, Client shall provide an opportunity for DU to cure the breach or end the violation within thirty (30) days, and may terminate this Agreement and the Service Agreement if DU does not cure the breach or end the violation within the time permitted.

5.3 Except as provided in Section 5.4, upon termination of this Agreement, for any reason, DU shall return or destroy all PHI received from Client, or created or received by DU on behalf of Client. This provision shall also apply to PHI that is in the possession of subcontractors or agents of DU. DU shall retain no copies of the PHI, except as provided in Section 5.4.

5.4 In the event that DU determines that returning or destroying the PHI is infeasible, DU shall provide to Client notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of PHI is infeasible, DU shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as DU maintains such PHI.

6. Indemnity

Client agrees to indemnify, defend and hold DU harmless from and against any and all claims or causes of action arising out of or in any way pertaining to the use or disclosure by DU of any PHI, provided that such use or disclosure is made in accordance with the terms of this Agreement.

7. Miscellaneous Provisions

7.1 Forum Selection. ANY LITIGATION BETWEEN THE PARTIES ARISING OUT OF OR RELATING TO THIS AGREEMENT MUST BE BROUGHT EXCLUSIVELY IN THE STATE OR FEDERAL COURTS LOCATED IN THE STATE OF WASHINGTON. THE PARTIES HEREBY WAIVE ANY AND ALL OBJECTIONS TO THE EXERCISE BY THE COURTS OF THE STATE OF WASHINGTON OF PERSONAL JURISDICTION OVER THEM, AND TO THE VENUE OF THE COURTS OF THE STATE OF WASHINGTON.

7.2 Successors and Assigns. This Agreement, and all rights and powers granted hereby, will bind and inure to the benefit of the parties hereto and their respective successors and assigns. For purposes of this Section, assignment by operation of law in connection with a merger, acquisition, asset sale, or other corporate reorganization shall be deemed an assignment. In the event of any assignment, the assignor shall remain liable and responsible for the performance of the obligations under this Agreement, and the assignee shall expressly (a) agree to be bound by the terms of this Agreement and (b) grant the other party enforcement rights against the assignee.

7.3 Notices. Any notices permitted or required by this Agreement will be deemed given when personally delivered or upon deposit in the United States mail, postage fully prepaid, certified, return receipt requested, addressed to the address specified on the Sales Agreement.

7.4 Compliance with the Laws. The parties understand and intend that the terms of this Agreement and their relationship comply with all applicable laws, ordinances, and regulations. Further, during the term of and with respect to their performance under this Agreement, each party will remain in compliance with all applicable laws, ordinances and regulations.

7.5 Integration and Priority. The ScanPoint Agreements, collectively, constitute the entire agreement between the parties as to their subject matter. There are no promises, terms, conditions, or obligations between the parties other than those contained in the ScanPoint Agreements. The ScanPoint Agreements supersede all prior communications, representations, and agreements, oral or written, of the parties with respect to their subject matter. In the event of a conflict among the ScanPoint Agreements, the terms of the Service Agreement shall be controlling, followed by the Terms and Conditions of Sale, followed by this Agreement, followed by the EULA. No modification of this Agreement will be valid unless in writing and signed by both parties.

7.6 Modification. No modification of this Agreement will be valid unless in writing and signed by both parties. The Parties agree to amend this Agreement from time to time as is necessary for Client to comply with the requirements of the HIPAA Privacy Rules and Public Law 104-191.

7.7 Interpretation. The section and paragraph headings of this Agreement are for the convenience of the reader only, and are not intended to act as a limitation of the scope or meaning of the sections and paragraphs themselves. This Agreement will not be construed against the drafting party. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Client to comply with the HIPAA Privacy Rules.

7.8 Severability and Waiver. The invalidity of any term or provision of this Agreement will not affect the validity of any other provision. Waiver by any party of strict performances of any provision of this Agreement will not be a waiver of or prejudice any party's right to require strict performance of the same provision in the future or of any other provision of this Agreement.

7.9 Governing Law. This Agreement will be interpreted and enforced according to the laws of the State of Washington and the United States of America.

7.10 No Third Party Beneficiaries. This Agreement creates no third party rights or obligations between DU and any other person. It is understood and agreed that the parties do not intend that any third party should be a beneficiary of this Agreement.

7.11 Counterparts. This Agreement may be executed in multiple counterparts, all of which together will constitute one agreement, even though all parties do not sign the same counterpart.

Health Insurance Portability and Accountability Act (HIPAA) Compliance Statement

To address the growing concern about the protection and confidentiality of an individual's medical information, The Verathon Corporation has taken the following measures to insure the safe delivery and storage of all information that is maintained, used, and presented by the ScanPoint® system:

- All ScanPoint communications across the Internet are transmitted using the *Secure Socket Layer* (SSL) protocol and the 128-bit *Data Encryption Standard* (DES).
- All *Patient Health Information* (PHI) specific data stored within the ScanPoint database is encrypted.
- The ScanPoint website infrastructure is housed by a Tier-1 *Network Service Provider* (NSP) that meets the SAS/70 certification.
- Within the NSP, the ScanPoint equipment is located in a "locked, steel cage" structure, removing access from even the NSP's personnel.
- The Verathon Corporation has enacted all policies and procedures outlined in HIPAA to protect our internal network from unauthorized access.

The Verathon Corporation has taken these actions to meet HIPAA's Privacy and Security requirements and shall continue to monitor any changes in these laws to insure all precautions are taken to protect PHI. For further information on how The Verathon manages access to PHI, refer to the Verathon Business Associates Agreement (0003-0138).

Term	Description
Activate	The act of turning on your instrument by placing the activation tool in the opening just above the Scan button. When your instrument has been completely discharged, sometimes activation will be necessary.
Activation tool	The small, metal tool used to activate your instrument.
Aiming arrows	Arrows located in the center of the scanning unit's LCD screen below the bladder volume measurement, which identify the location of the bladder relative to the scanhead. A flashing aiming arrow means re-aiming is required. A solid aiming arrow means re-aiming is optional.
Calibration	The act of checking the accuracy and system functionality of a measuring instrument by comparing it with a known standard.
Calibration targeting system	A system used for calibration purposes consisting of a calibration container holding a spiral-shaped calibration target. The calibration system provides a known reference in a spherical coordinate system, which in normal operation allows the device to provide accurate volume measurements.
Charging cradle	The cradle that is used to charge the battery of the scanning unit; this cradle plugs directly into an electrical wall outlet.
Communication cradle	The cradle that plugs into any personal computer through a standard USB connection and enables the scanning unit to communicate with the computer. This cradle can also be used to recharge the battery of the scanning unit when the connected computer is turned on.
Coupling medium	A substance, such as ultrasound gel, that facilitates the transmission of ultrasound waves.
Flashing aiming arrow	A flashing arrow may appear on the scanning unit's LCD screen when part of the bladder is outside the scanning unit's field of vision. A flashing arrow indicates that you must re-aim the instrument and re-scan the patient to obtain the highest degree of accuracy.
Gel pad	A disc-shaped, gel-filled pad that facilitates the transmission of ultrasound waves.
Image cone	The cone-shaped range within which ultrasound waves are transmitted by the scanhead when scanning the bladder.
IR Window	The window, located at the base of the handgrip, which enables the scanning unit to connect with your computer via the communication cradle.
Labeling	The square label, located below the Scan button on the scanning unit, that provides important product information, including the name, product and serial numbers, and instrument classifications.
LCD screen	The LCD (liquid crystal display) screen on the scanning unit that displays the bladder volume measurement and other scan, patient, and instrument data.

Term	Description
Neurogenic	Caused or affected by the nervous system.
Repeatability	The process of repeating a scan multiple times in order to get more accurate exam results.
Scan button	The button, located on the underside of the scanning unit's handgrip, which initiates the bladder volume measurement.
Scanhead	The portion of the scanning unit, attached above the handgrip, through which ultrasound energy is transmitted to the patient.
Scanning unit	The handheld instrument, including the scanhead and handgrip, which transmits ultrasound energy to produce an image of the patient's bladder and determine bladder volume.
ScanPoint®	Online service provided by The Verathon Corporation. Allows BladderScan® operators to print exam results, maintain patient records, view ultrasound images from exams, download software updates, and calibrate the scanning unit.
Sleep mode	The scanning unit appears to be off. Press any button to re-activate.
Solid aiming arrow	A solid arrow indicates an aiming suggestion. The solid arrow appears on the scanning unit's LCD screen below the bladder volume measurement when the instrument senses that the bladder was not completely centered in its field of vision. In this case, re-aiming is optional but not required.
Supine position	Lying on the back with the face upward.
Supra-pubic	Situated above the pubic bone.
Symphysis pubis	The part of the human body where the pubic bones meet in the front of the pelvis.
Top (Gender) button	The button located below the scanning unit's LCD screen. This button allows the user to select various settings and perform different functions, depending on the device model. For example, it is used to select or deselect the female setting when measuring bladder volume with the BVI 6100, BVI 6200, BVI 6400, and BVM 6500, to select the pre-void or post-void option when using the BVI 6300, to record a voice annotation with the BVI 6400, to initiate a calibration measurement, and to display the days remaining until calibration.
UEBW	Ultrasound estimated bladder weight. Metric indicating bladder wall thickness, used to diagnose bladder hypertrophy.
Ultrasonic	Involving ultrasound; ultrasound refers to acoustic frequencies above the range that can be heard by the human ear.

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